104

EFFECTS OF ANESTHESIA DURING A PARTIAL-BIRTH ABORTION

Y 4. J 89/1: 104/73

Effects of Anesthesia During a Part...

RING

BEFORE THE

SUBCOMMITTEE ON THE CONSTITUTION

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

MARCH 21, 1996

Serial No. 73

OCT 0 2 1996

Printed for the use of the Committee on the Judiciary

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EFFECTS OF ANESTHESIA DURING A PARTIAL-BIRTH ABORTION

THURSDAY, MARCH 21, 1996

House of Representatives,
Subcommittee on the Constitution,
Committee on the Judiciary,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:40 a.m., in room 2141 Rayburn House Office Building, Hon. Charles T. Canady (chairman of the subcommittee) presiding.

Present: Representatives Charles T. Canady, Henry J. Hyde, Bob Inglis, Michael Patrick Flanagan, F. James Sensenbrenner, Jr., Bob Goodlatte, Barney Frank, John Conyers, Jr., and Patricia Schroeder.

Also present: Kathryn A. Hazeem, chief counsel; Keri D. Harrison, assistant counsel; Jacquelene McKee, paralegal; Mark Carroll, staff assistant; and Robert Raben, minority counsel.

OPENING STATEMENT OF CHAIRMAN CANADY

Mr. Canady. The subcommittee will be in order.

It is unfortunate that we are forced to take time out of our busy schedule today to examine one of the myths created by abortion advocates about partial-birth abortion, but I believe that it is important to the health of pregnant women to set the record straight.

Shortly after H.R. 1833, the Partial-Birth Abortion Ban Act, was introduced, abortion advocates began to claim that anesthesia given to the mother at the beginning of a partial-birth abortion kills the unborn child. Based on this myth, they argue it is misleading to call the procedure a partial-birth abortion and any concern that the child experiences pain during the procedure is misplaced.

The claim was originally disseminated by the National Abortion Federation, a group representing abortion providers. A federation factsheet says, "Antiabortion groups claim that the fetus is still alive until the very end of the procedure. This is absolutely untrue. Neurological fetal demise is induced either before the procedure begins or early on in the procedure by taking steps to prepare the women for surgery. This includes narcotic analgesia, extensive cervical dilation, and rupture of the membranes. Dr. McMahon calls the statements to the contrary preposterous. Dr. Martin Haskell of Ohio agrees with Dr. McMahon's assessment. . . . In the event that there is any possibility of pain perception in later-term fetuses prior to fetal demise, the narcotic analgesia given to the pregnant women prevents any such sensation."

Another leading proponent of the anesthesia myth is Kate Michelman, president of the National Abortion Rights Action League, who was invited to testify today, but indicated that she had a previous commitment. In an interview on Newsmakers in St. Louis on November 2 of last year, Ms. Michelman said, "[T]he other side grossly distorted the procedure. There is no such thing as partial-birth abortion. That's a term made up by people like these antichoice folks that you had on the radio. The fetus, I mean, it is a termination of the fetal life. There is no question about that, and the fetus is, before the procedure begins, the anesthesia that they give the women already causes the demise of the fetus. That is, it is not true that they are born partially. This is a gross distortion, and it's really a disservice to the public to say this."

Dr. Mary Campbell of Planned Parenthood circulated a factsheet titled, "H.R. 1833, Medical Questions and Answers," which includes this statement, "Question: when does the fetus die? Answer: the fetus dies of an overdose of anesthesia given to the mother intravenously. A dose is calculated for the mother's weight which is 50 to 100 times the weight of the fetus. The mother gets the anesthesia for each insertion of the dilators twice a day. This induces brain death in a fetus in a matter of minutes. Fetal demise therefore occurs at the beginning of the procedure while the fetus is still in the womb."

The press accepted abortion advocates' claims as fact and promulgated the anesthesia myth. U.S. Today claimed, "The fetus dies from an overdose of anesthesia given to its mother." And the St. Louis Post-Dispatch reported, "The fetus usually dies from the anesthesia administered to the mother before the procedure begins." The New York Daily News editorialized, on December 15, as follows, "The fetus is partially removed from the womb, it's head collapsed, and brain suctioned out so it will fit through the birth canal. The anesthesia given to the woman kills the fetus before the full procedure takes place. But you won't hear that from the anti-abortion extreme. It would have everybody believe that the fetus is dragged alive from the womb of a woman just weeks away from birth. Not true." Syndicated columnist, Ellen Goodman, wrote in mid-November that "if one relied on statements by supporters of the bill, you wouldn't even know that anesthesia ends the life of such a fetus before it comes down the birth canal."

Members of Congress have also relied on abortion advocates for information and neglected to check their facts, repeatedly arguing that the child in a partial-birth abortion is killed by anesthesia before the procedure begins.

But Dr. Norig Ellison, the president of the American Society of Anesthesiologists, says that this claim has "absolutely no basis in scientific fact." Dr. David Birnbach, the president-elect of the Society for Obstetric Anesthesia and Perinatology, says it is "crazy." We are looking forward to hearing testimony of both Dr. Ellison and Dr. Birnbach today.

Despite these and other authoritative statements to the contrary, the medical misinformation is still being disseminated. The American Medical News reported the controversy in a January 1 article which stated, "Medical experts contend the claim"—regarding anesthesia—"is scientifically unsound and irresponsible, unnecessarily worrying pregnant women who need anesthesia." But while some are now qualifying their assertion that anesthesia induces fetal death, they are not backing away from it.

Abortion advocates have repeatedly denied or misrepresented the facts on partial-birth abortion. While I do not believe that any misrepresentation is acceptable, the creation of this anesthesia myth is particularly unconscionable. It could cause women who are pregnant to refuse anesthesia for needed medical treatment because they fear it will harm or kill their unborn child.

Dr. Ellison has stated, "I am deeply concerned that widespread publicity may cause pregnant women to delay necessary and perhaps life-saving medical procedures totally unrelated to the birthing process due to misinformation regarding the effect of anesthetics on the fetus."

I believe it is important for us to fully examine this issue today—to put an end to this myth, and to ensure that pregnant women know their unborn children are not endangered by anesthesia.

[Additional information follows:]

LATER ABORTIONS: QUESTIONS AND ANSWERS

Now pending in Congress are two bills, H.R. 1833 and S. 939, which would ban a particular type of later abortion procedure. Those promoting these bills have used sensationalized drawings and graphic language to attempt to inflame opposition to this surgery. They have left out or distorted the realities that lead to a difficult abortion decision late in pregnancy; the facts about how this procedure is performed; and how rarely this surgery takes place. The National Abortion Federation (NAF) is the national professional association of abortion providers. We set standards for quality care and provide accredited continuing medical education. In this set of questions and answers, NAF will provide the facts about these later abortions and the personal and political context surrounding this issue.

How often do later abortions happen?

Statistical information compiled by the Alan Guttmacher Institute, a private institution for reproductive health research and policy analysis, and the National Abortion Federation (NAF), documents the following:

The overwhelming majority -- 95.5 percent -- of all abortions take place at or before 1 weeks' gestation, in the first or very early second trimester. About 90% of these are in the first trimester. Only a little over 1/2 of one percent of all abortions take place at or after 20 weeks' gestation. Fewer than 600 abortions per year occur in the third trimester of pregnancy, and all of these are performed due to severe fetal abnormality or risk to the life of the pregnant woman.[1]

What does this tell us? It tells us that virtually all women seeking abortions are do so early in pregnancy -- that women do not want to have later abortions. Women do end a pregnancy at any stage, particularly a later one, lightly or cavalierly. Sometimes though, unavoidable circumstances force them to confront this decision, and they make it responsibly, carefully, with a great deal of thought.

---

[1] Henshaw, S.K. and Van Vort, J., eds. *Abortion Factbook*. The Alan Guttm Institute, 1992. Also, The National Abortion Federation, quarterly statistical 1994.

Executive Director: Vicki A. Saporta   President: [illegible]   President-Elect: [illegible]
Board Members: [illegible]

changes they notice reflect early menopause; or they may have irregular menstrual cycles and so few physical changes early on that they are not aware they are pregnant until the second trimester.

Still others are victims of burdensome laws that, rather than improving women's health care, merely mandate medically unnecessary delays. Since the passage of laws mandating parental involvement in the abortion decision, Minnesota and Mississippi have seen the ratio of late to early abortions for teenagers increase by over 25% and 18% respectively.[9] Though over 60% of all teenagers consult a parent about their abortion decision[10], those who do not often have legitimate fears about doing so. Restrictive laws that ignore these fears lead to later abortions.

Laws that mandate waiting periods before a woman can obtain an abortion also lead to unnecessary delays in obtaining care. A "simple" 24-hour waiting period, combined with a woman's other circumstances and limited provider access, in practice often means delays of a week or more.[11] Such laws are promoted by anti-abortion groups.

It would be inhumane and medically inappropriate to pass a federal law which would limit women's medical options in these difficult situations. Burdensome laws do not prevent women from having later abortions; indeed, the documentation above indicates that other anti-abortion laws are responsible for **increases** in later abortions. The proposed legislation would only increase the physical and emotional risks to the women involved.

What are the misconceptions about this procedure?

- Anti-abortion groups claim that the fetus is still alive until the very end of the procedure. This is absolutely untrue. Neurological fetal demise is induced, either before the procedure begins or early on the procedure, by the steps taken to prepare the woman for surgery. (This includes narcotic analgesia, extensive cervical dilation, and rupture of membranes.) Dr. James McMahon of California calls statements to the contrary preposterous. Dr. Martin Haskell of Ohio agrees with Dr. McMahon's assessment and submitted a written statement to that effect [illegible]

---

[9] "Percent Abortions of Second Trimester: Minnesota Residents," Plaintiff's Exhibit 122, *Hodgson v. Minnesota* 648 F. Supp. 756 (D. Minn. 1986). Also, Althaus, F. and Henshaw, S.K., "The Effects of Mandatory Delay Laws on Abortion Patients and Providers," *Family Planning Perspectives*, Sept./Oct. 1994.

[10] S. Henshaw and K. Kost, "Parental Involvement in Minors' Abortion Decisions," *Family Planning Perspectives* Vo. 24, No. 5 (Sept./Oct. 1992).

[11] Althaus, F. and Henshaw, S.K. Op. cit.

Congressman Charles Canady, Chair of the House Judiciary Subcommittee on the Constitution, following the Subcommittee's hearings on the legislation.

- Anti-abortion groups have also asserted that the fetus in these cases feels pain. Neurologically, according to commentary by neurologist Dr Dominick Purpura, Dean of the Albert Einstein Medical School, the synaptic connections that would permit perception of pain do not exist until around the 28th week of gestation[12]. In the event that there is any possibility of pain perception in later-term fetuses prior to fetal demise, the narcotic analgesia given to the pregnant woman prevents any such sensation.

Of course, most of the information quoted by the anti-abortion politicians advocating this ban is several years old, and in most cases, involves brief quotes in secondary source materials such as newspaper articles. The physicians who perform this procedure have unequivocally refuted these anti-choice arguments in materials presented directly to the Congressional committee considering this legislation. Haskell noted in his letter to the Subcommittee that public officials should be aware that often, when quoted in public, a person's remarks are misrepresented, misunderstood or taken out of context. He wrote "Let me state unequivocally that taken as a whole these lay articles are misleading and misrepresent the nature of this surgery. Articles written for the professional community take for granted a certain amount of knowledge in the reader. Consequently they do not describe every detail."[13]

Is this legislation constitutional?

In-depth legal analysis by the Center for Reproductive Law & Policy clearly indicates that this legislation, known by the misnomer "The Partial-Birth Abortion Ban Act of 1995", is clearly unconstitutional under the standard set forth by the Supreme Court in Planned Parenthood of Southeastern Pennsylvania v. Casey (1993). The Center's analysis states "The bill would impose an undue burden...by limiting the physician's discretion to choose the most appropriate method of abortion based on the medical needs of his or her patient. The Supreme Court has consistently held that physicians must retain broad discretion to determine the course of treatment for women seeking abortions."[14]

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[12] Jaworski, P., moderator. "Thinking About 'The Silent Scream,'" as transcribed in Abortion Rights and Fetal 'Personhood', Ed Doerr, ed., Centerline Press, 1989

[13] Haskell, M., MD. Letter to Congressman Charles D. Canady, Chair, House Judiciary Subcommittee on the Constitution, June 27, 1995.

[14] Kolbert, K. Op. cit.

KMOX-AM, St Louis, MO
November 2, 1995
Program: KMOX "Newsmakers"
Host: Charles Jaco
Topic: Partial-Birth Abortion Ban Bill passes in the United States House of Representatives

Charles Jaco: "What about the claim, I'm sorry to interrupt you, but, what about the claim from people like Mary Kay Culp of Missouri Right to Life who, when I asked her about this a few minutes ago, said 'Au contraire, that 80 per cent of these procedures are elective.' "

Kate Michelman: "...The other thing that I want to say is that they have, the other side, grossly distorted the procedure, and, they, there is no such thing as a partial-birth. That's, that's a term made up by people like these anti-choice folks that you had on the radio. The, the fetus, I mean it is a termination of the fetal life, there's no question about that, and the fetus, is, before the procedure begins, the anesthesia that they give the woman already causes the demise of the fetus, that is, it is not true that they're born partially. That is a gross distortion and it's, it's really a disservice to the public to say this."

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TRANSCRIPT
November 07, 1995
NEWS CONFERENCE
KATE MICHELMAN
NATIONAL ABORTIONS RIGHTS ACTION LEAGUE
WASHINGTON, D.C.
NEWS CONFERENCE TO ANNOUNCE OPPOSITION TO LATE TERM ABORTION.

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NATIONAL ABORTION AND REPRODUCTIVE RIGHTS ACTION LEAGUE (NARAL) NEWS CONFERENCE TO ANNOUNCE OPPOSITION TO LATE TERM ABORTION BILL

NOVEMBER 7, 1995

SPEAKERS LIST: KATE MICHELMAN, PRESIDENT, NARAL
JO BLUM, LEGISLATIVE DIRECTOR, NARAL
MARCY WILDER, LEGAL DIRECTOR, NARAL

MICHELMAN: Good morning everyone. Thank you very much for coming. My name is Kate Michelman and I'm president of NARAL, the National Abortion and Reproductive Rights Action League. And we asked you here today have an opportunity to talk about the very serious development that occurred in the House last weekend that will be taken up by the Senate today.

The Senate today is taking up the House-passed bill that would ban some late term abortions. This legislation will harm woman's health and could send doctors to jail as common criminals. It presents a direct constitutional challenge to Roe versus Wade and sets a very dangerous precedent because it contains absolutely no exception to protect a woman's life or her health.

With this bill, we stand at one of the most critical moments in the history of the fight for reproductive freedom that we have seen since the last 22 years. It is the first time since the Supreme Court legalized abortion and recognized a woman's constitutional right of choice that the Congress of the United tried to offer that amendment. The bill was brought up, as you all know, on the House floor with a closed rule in order to prevent that very amendment from being offered. We expect, should the bill come to the, when the bill comes to the floor in the Senate, if the Judiciary Committee hasn't amended it to include life and health exceptions, if it goes back to Judiciary Committee, that if that would be -- it's not clear that that exception would be added, even in the Senate.

Should it be added in the Senate, we don't see that the House would accept that because they refused to allow a vote on it, and the anti-abortion leaders have made it very clear that they want no exceptions.

MICHELMAN: That's right. I think that the very procedure that the House carried out -- proceeding on a closed rule, not allowing any amendments to the bill that would provide health and life exceptions -- just makes clear what their goal is, which is to make abortion procedures illegal and their goal to make abortions unavailable to women in this country.

QUESTION: Are these fetuses alive? You touched on that earlier. Or are they killed by some other means before?

MICHELMAN: There has been expert testimony by physicians who do this procedure, stating that the anesthesia that is given to the pregnant woman, prior to the procedure, causes fetal demise -- the death of the fetus -- prior to the procedure. Again, these are difficult procedures to talk about, but we have to try to remember these are extraordinary medical circumstances that call for extraordinary intervention.

But see
Dr. Ellison,
A.S.A.
testimony

And no procedure, no matter how we describe it, no matter what the procedure is, it's not a comfortable procedure. But in this particular case, these experts have made it very clear that the fetus undergoes demise before the procedure begins. And because of the anesthesia, which is, you know, something like 50 to 100 times what a fetus can withstand, because it's given according to the weight of the woman. And that's the procedure.

QUESTION: One of the arguments was that these procedures, though, are given for depression or a cleft palate.

MICHELMAN: That is -- that is -- that is -- it's not only a myth, it is a lie. It is insulting. Women, these are women carrying wanted pregnancies. And the reason they're late is

Dr. McMahon's
sample of
"maternal
indications"
shows 22% were
for "depression"!

H.R. 1833

Medical Questions and Answers

Q: What is a "partial birth abortion"?

A: Who knows? Not doctors. "Partial birth abortion" is a term made up by the authors of H.R. 1833/ S. 939 to suggest that a living baby is partially delivered and then killed.

The term is not found in any medical dictionaries, textbooks, or coding manuals. The definition 1531(b) of H.R. 1833 is so vague as to be uninterpretable, yet chilling. Many OB/GYNs fear this language could be interpreted to ban all abortions where the fetus remains intact. One procedure this bill would certainly ban is intact D&E (Dilation and Evacuation).

Q: When is intact D&E used?

A: As early as 12 weeks but most commonly in the second trimester between 20 and 24 weeks. It is also sometimes used in the third trimester.

Q: Are late term abortions common?

A: No, not at all. 95.5% of abortions take place before 15 weeks. Only a little more than one-half of one percent take place at or after 20 weeks. Fewer than 600 abortions per year are done in the third trimester and all are done for reasons of life or health of the mother including severe fetal abnormality.

Q: What are the maternal problems which cause women to seek late abortions?

per year are done in the third trimester and all are done for reasons of life or health of the mother including severe fetal abnormality.

Q: What are the maternal problems which cause women to seek late abortions?

A: Certain maternal problems would probably kill or disable the mother if the pregnancy continued, for example severe heart disease, kidney failure, or rapidly advancing cancer. Many of these women are literally dying to have a baby, but pregnancy affects diseases in unpredictable ways, and a woman can find herself carrying a wanted pregnancy which may cause her death.

(3)

Q: Why not induce labor with drugs?

A: The cervix, which holds the uterus closed during pregnancy, is very resistant to dilation until about 36 weeks. Inductions done before this time take between two to four days. Induction is also a physically painful process. Because of the danger of uterine rupture, inductions require constant nursing supervision and are therefore done on the labor and delivery ward. The physical pain is intensified by the emotional pain of losing a wanted pregnancy while spending days listening to newborns make their first cries and other families cheer and cry in delight.

Q: Why not just do a caesarean?

A: A caesarean delivery generally involves twice as much blood loss as a vaginal delivery. Before 34 weeks gestation the lower segment of the uterus is usually too thick to use a standard horizontal incision, so a vertical incision is necessary. Any uterine incision complicates future pregnancy, but a vertical incision is more dangerous and jeopardizes both the mother's health and any future pregnancies When the uterus has a vertical scar, future pregnancies require a caesarean and are more apt to be complicated by uterine rupture.

Q: Is there a safer and better option?

A: Yes. Using the intact D&E procedure, a doctor can put into the cervix small dry cylinders that expand as they absorb fluid from the mother, causing gradual expansion of the cervix overnight. The patient can return home except for twice daily clinic visits to ensure that she is dilating and to replace the osmotic dilators if more dilation is required. She receives intravenous anesthesia for the insertion of the dilators as well as for the procedure.

The procedure can be accomplished with less dilation -- which means less trauma to the cervix and less chance of problems in the next pregnancy -- if some of the fluid is removed from the fetal head, (which is the largest part of the fetus) by using a spinal needle for aspiration. This technique reduces the chances of lacerating the cervix which contains large blood vessels.

Q: When does the fetus die?

A: The fetus dies of an overdose of anesthesia given to the mother intravenously A dose is calculated for the mother's weight which is 50 to 100 times the weight of the fetus.

The mother gets the anesthesia for each insertion of the dilators, twice a day. This induces brain death in a fetus in a matter of minutes. Fetal demise therefore occurs at the beginning of the procedure while the fetus is still in the womb.

Q: Are there any benefits to intact D&E besides lessened maternal pain, trauma, blood loss, and chance of clotting problems?

A: Yes. Intact delivery allows the geneticists, pathologists, and perinatalogists to determine what exactly this baby's problems were. This is very important for advising the parents about future pregnancy and for collecting information that will allow medical researchers to prevent such problems for other women in the future.

Also, when the baby is delivered intact the family is able to see and to hold the baby to say goodbye to someone they loved, if this will help them with their grieving process.

FACT SHEET PREPARED BY:

Mary Campbell, MD
  Medical Director, Planned Parenthood of Metropolitan Washington
  Fellow of the American College of Obstetricians and Gynecologists
  Member, National Abortion Federation
  MD, The Johns Hopkins University, 1977
  Residency in OB/GYN - Georgetown University Hospital, 1981-84
    - Sinai Hospital of Baltimore, 1979-1981
  Masters in Public Health, The Johns Hopkins University, 1979

if they share them with us, and they tend to. So it's not a matter of whether or not we know, it's a matter of whether or not we think that this is an appropriate way to take care of this kind of situation, whether or not it's also safe for the mother.

People have said that this procedure is safe. This procedure is not safe in an outpatient facility. One of the side effects of it that is known is that the woman could die.

SIMPSON: Well, I respectfully say then somebody tell me, before me we're all finished, how this can be performed in a state and not outside or in interstate commerce? I mean, that is bizarre beyond comprehension.

HATCH: All right, Senator Abraham. You're the final questioner here.

* ABRAHAM: Thank you, Mr. Chairman. I think probably Senator Simpson might want to direct that last question on the interstate issue to the final panel, because my suspicion is it's more a constitutional issue than it is one that this panel can address.

But let me ask Dr. Campbell a question. Earlier, we heard from Dr. Ellison, he commented rather extensively on the issue of the basis on which the fetus dies and specifically said that it is not related to the anesthesia that the mother receives.

Would you care to comment on that? Do you agree with him?

CAMPBELL: I think it is related to the anesthesia the mother receives. I agree with him that anesthesia in pregnancy has made incredible leaps over the last 20 years and that women can undergo surgery which is safe for their offspring during surgery.

One of the things that he mentioned that makes this possible is regional anesthesia, where the anesthetic agent is confined around mom's spinal cord and does not go into the blood system.

CAMPBELL: The other part of his testimony which I found relevant

SENATE JUDICIARY HEARING, 11/17/95, PAGE 104

is he said a dose adequate for pain relief and sedation in mother would not harm an uncompromised infant.

These are compromised infants, many of whom have anomalies that would make it impossible for them to breathe on their own outside. I do not know whether or not these infants are quote/unquote "brain dead" when born. I know that they are sedated. I've not seen any spontaneous movement.

I've asked people who worked in Dr. McMahon's office. They said they have not, in their 2,000 procedures, seen any spontaneous respirations. I believe that the fetus is not in pain.

ABRAHAM: But I mean, so you would be able to -- would you make the statement then that the fetus dies due to the anesthesia? Is that your position?

CAMPBELL: I think the fetus has no pain because of the anesthesia. I do not...

ABRAHAM: No, I'm asking you whether you think that's what causes the fetus to die?

CAMPBELL: I do not know what causes the fetus to die. The fetuses are dead when delivered.

ABRAHAM: Well, let me just direct you, if I could -- I have here a fact sheet that indicates it was prepared by you which relates to the House legislation in which...

CAMPBELL: I was quoting Dr. McMahon at that time. On thinking it over in more depth, I believe because there are no EEG studies available...

ABRAHAM: So you no longer adhere to the position that you say in here the fetus dies of an overdose of anesthesia given to the mother intravenously. That is no longer your position?

CAMPBELL: I believe that is true.

SENATE JUDICIARY HEARING, 11/17/95, PAGE 105

ABRAHAM: You believe that is true?

CAMPBELL: I believe that is true.

ABRAHAM: Dr. Ellison, would you like to comment on that?

ELLISON: There is absolutely no basis in scientific fact for that statement. There is -- I can present you a study in the American Journal of Obstetrics and Gynecology, 1989, by (OFF MIKE) et al, of 5,400 cases of women having surgery having general anesthesia or regional anesthesia in which the fetus did not suffer demise.

I think the suggestion that the anesthesia given to the mother, be it regional or general, is going to cause brain death of the fetus is without basis of fact.

CAMPBELL: I have not said brain death. I'm saying no spontaneous respirations, no movement.

ABRAHAM: Well, that's what you are saying today, but in this fact sheet, which you prepared I believe fairly recently, it says, "The fetus dies." There's no qualifying regarding breathing or anything else, "Of an overdose of anesthesia."

I mean, that is a very clear statement assertion.

CAMPBELL: I simplified that for Congress. I do not actually believe that you want a full discussion of when death occurs.

ABRAHAM: Well, we are forced to make those decisions, and I guess my question is that how many other things would you say in the fact sheet or in your statements today have been likewise simplified in this dramatic fashion?

CAMPBELL: Since I have over 28 years of education and experience in medicine, I would say that is a great deal less and a great deal more simple than what I know.

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ABRAHAM: Well, it seems to me that there's a rather substantial disparity between what Dr. Ellison says and what you are both saying now and have certainly written here. I just am wondering how that bears on other comments that have been made.

Let me ask Dr. Robinson a question. Dr. Robinson, how many abortions have you performed?

ROBINSON: In my course of 40 years of practice, I'm afraid I cannot answer that any more than I could answer how many hysterectomies or how many babies I've delivered.

ABRAHAM: Can you put it into general? You know, like is it more than 100?

ROBINSON: Oh, yes.

ABRAHAM: More than a thousand?

ROBINSON: Probably -- oh, definitely, yes.

ABRAHAM: More than 5,000?

ROBINSON: We're creeping up to a number that I can't estimate.

ABRAHAM: But it could be more than 5,000?

ROBINSON: Oh, yes. This has been something I've done. I've supported women and their rights to choose for a long time.

ABRAHAM: I just -- my question, I'm laying the groundwork for a separate question that I wanted to also ask you. The procedure we've heard described here by various people -- the Dr. Haskell procedure. I won't try to define it better than that because I'm one of these simple guys here in Congress.

But the Haskell procedure -- how many of those procedures do you believe are performed on an annual basis in this country?

Senator Barbara Boxer
Hart Senate Office Building
Suite 112
Washington, DC 20510

Dear Senator Boxer:

During the Senate Judiciary Committee hearings on HR1833, Dr. Norig Ellison stated clearly that neither he, nor the American Society of Anesthesiologists whom he represents were taking a position on the bill in question. His purpose was to assure pregnant women who discover that they need surgery that they can, in fact, undergo anesthesia in treatment of their own conditions that will not harm their developing fetuses. This fact is not under dispute, since as Dr. Ellison points out, and as any physician understands, the effect a drug will have on a fetus depends on 1) fetal condition, 2) the route of drug administration, and 3) the timing.

In the case of late-term D&X abortion, the drug combination most frequently used has been intravenous Versed (10-40 mg, given in 1-2mg increments) and Fentanyl (900-2500 ug, given in 100-150 ug increments) over a 1-3 hour period. The total dose and timing vary with the woman's weight and condition. These drugs have been documented to cross the placental circulation to the fetus. Though these total doses are high, the incremental administration of the drugs minimizes the probability of negative outcomes for the mother. In the fetus, these dosage levels may lead to fetal demise (death) in a fetus weakened by its own developmental anomalies. In other cases these drugs prevent the perception of pain by the fetus; they cause depression of fetal respiration before the extraction procedure and preclude fetal respiration afterward.

Sincerely,

Mary Campbell, MD

Mary Campbell, MD

American Medical
NEWS

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Anesthesiologists question claims in abortion debate

By Diane M. Gianelli
AMNEWS STAFF

WASHINGTON — When he saw an article in the *St. Louis Post-Dispatch* that claimed anesthesia caused fetal death in some late-term abortion procedures, David Birnbach, MD, was "shocked."

"I thought, 'This is crazy!' " said Dr. Birnbach, who is director of obstetric anesthesiology at New York's St. Luke's-Roosevelt Hospital Center, and vice president of the Society for Obstetric Anesthesia and Perinatology.

"Everyday we have pregnant patients who get anesthesia — women who break their ankles, need knee surgery, have appendectomies, gallbladder removals, breast biopsies, and so on. Anesthetics done safely by an anesthesiologist do not do harm to either the mother or the baby," he said.

The anesthesia-causes-fetal-death claim was made by one of the two U.S. physicians who specialized in a particular type of late-term abortion that opponents call "partial birth" abortions. The contention has been repeated by other proponents of the procedure, who refer to it as "intact D&E" (for dilation and evacuation) or "D&X" (dilation and extraction).

Medical experts contend the claim is scientifically unsound and irresponsible, unnecessarily worrying pregnant women who need anesthesia. But while some are now qualifying their assertion that anesthesia induces fetal death, they are not backing away from it.

When Rep. Charles T. Canady (R, Fla.) introduced a bill to ban the procedure, James T. McMahon, MD, a Los Angeles area family physician who specialized in this procedure before his recent death, responded. Dr. McMahon wrote that the anesthesia given to the mother before the abortion causes "neurological fetal demise."

The bill to ban the procedure, passed late last year by both the House and the Senate, defines it as one in which the provider "partially vaginally delivers a living fetus before killing the fetus and completing the delivery."

The procedure was recently banned in Ohio, where its other main practitioner, Martin Haskell, MD, lives. But a federal judge declared the law there unconstitutional in a preliminary injunction last month.

On the federal level, the bill faces a presidential veto threat, and while the measure passed the House by a 2-to-1 ratio, proponents do not have enough Senate votes to override a veto.

The claim about anesthesia causing fetal death has been repeated by many of the bill's opponents, including the National Abortion Federation, the National Abortion and Reproductive Rights Action League, and members of Congress. A recent Planned Parenthood "fact sheet" on these late-term abortions claims that "the fetus dies from an overdose of anesthesia given to the mother intravenously."

The distinction of when fetal death occurs is critical, because the bill would ban only procedures in which the fetus was killed after being partially delivered alive through the birth canal. If it could be proved that the fetuses died inside the womb — from anesthesia or any other cause — the abortion would not fall under the proposed law.

After reading the anesthesia-kills-fetuses claim in the St. Louis paper, the American Society of Anesthesiologists issued a press release denouncing it. And in testimony before the Senate, Norig Ellison, MD, president of the society — which did not take a position on the bill — called Dr. McMahon's statements "entirely inaccurate."

He added that he was "deeply concerned" that the widespread publicity given to Dr. McMahon's claims "may cause pregnant women to delay necessary and perhaps even life-saving medical procedures, totally unrelated to the birthing process, due to misinformation regarding the effect of anesthetics on the fetus."

In fact, cases of maternal concern have already surfaced. Dr. Birnbach said he has already had patients raise questions. And Rep. Tom Coburn, MD, an Oklahoma Republican who still delivers babies when he goes home on weekends, said he just had a patient refuse epidural anesthesia during childbirth after hearing those claims. Dr. Coburn is a co-sponsor of the bill.

Dr. Ellison, vice chair of the Dept. of Anesthesiology at the University of Pennsylvania School of Medicine in Philadelphia, testified that very little of the anesthetic given the mother ever reaches the fetus. He added that "in my medical judgment, it would be necessary — in order to achieve 'neurological demise' of a fetus in a 'partial birth' abortion — to anesthetize the mother to such a degree as to place her own health in serious jeopardy."

Planned Parenthood's Mary Campbell, MD, who wrote the fact sheet claiming anesthesia causes fetal death, was grilled during the Senate Judiciary Committee hearing Nov. 17, 1995, by Sen. Spence Abraham (R, Mich.).

When prodded, she conceded "I do not know what causes the fetus to die." When asked why her fact sheet attributes the cause to anesthesia, she replied, "I simplified that for Congress."

After the hearing, Dr. Campbell wrote to Sen. Barbara Boxer, (D, Calif.), who led the movement against the bill in the Senate. In her letter, Dr. Campbell repeated that anesthesia

cont. on next page..

caused fetal death, but added some caveats. She said it "may lead to fetal demise (death) in a fetus weakened by its own developmental anomalies."

"In other cases," she wrote, "these drugs prevent the perception of pain by the fetus; they cause depression of fetal respiration before the extraction procedure and preclude fetal respiration afterward."

Dr. Birnbach disputes her contention. Even in the very high-end doses she mentioned, he said — 10 mg to 40 mg of Versed, given in 1 mg to 2 mg increments, and 900 ug to 2,500 ug of fentanyl, given in 100 ug to 150 ug increments — "anesthesia does not kill an infant if you don't kill the mother."

He added that when patients receive the high-end dosage range specified by Dr. Campbell, the mother was in fact at risk for depressed breathing. "You can't give those high doses without harming the mother unless the mother is assisted in her breathing," he said.

Dr. Birnbach said that, on occasion, he has given even larger doses than the high-end ones cited by Dr. Campbell and has never caused any harm to either the mother or the fetus.

He also said that Dr. Campbell's claims that the medications depress fetal respiration before the abortion takes place were "immaterial" because fetuses don't breathe in the womb.

Dr. Birnbach added, however, that an infant born alive with depressed respiration can still survive normally. "The narcotics are not a problem. We can reverse the narcotics and we can breathe for the baby."

Another recurring theme at both the hearings and during the ensuing debate about the procedure centers around fetal pain. Specialists in this procedure claim the fetus feels no pain for a variety of reasons, but usually because they say fetuses lack the neural development necessary to perceive pain, or if they are capable of feeling pain, anesthesia given to the mother prevents the perception of pain in the fetus.

Robert J. White, MD, PhD, professor of neurosurgery at Case Western University in Cleveland, testified on the topic before Congress last summer. "There are published scientific studies that demonstrate that by the 20th week, many of the neuronal pathways that sense pain have already started to develop," he said. "By the 24th week, the connections of the cortex and the thalamus are well under way. . . . There is no way to argue with impunity that pain reception is not possible."

Michael J. Murray, MD, an anesthesiologist at the Mayo Clinic in Rochester, Minn., and president of the Minnesota Medical Assn., agrees.

In fact, he said, physicians doing fetal surgery inject narcotic fentanyl and muscle relaxants into the umbilical cord to provide pain relief, even though the mother is already anesthetized, "because what they get from the mom is not enough." He added that studies on neonates getting surgery right after birth indicate that those who were given opioids had much better outcomes than those who were just given muscle relaxants.

The bottom line for many anesthesiologists, regardless of their position on abortion: Women should not be concerned about questionable claims thrown out in the heat of the debate.

"Women who need anesthesia for emergency surgery during pregnancy or who request analgesia for labor should take heart that both they and their babies will do just fine," Dr. Birnbach said.

Mr. Frank.

Mr. **Frank**. Mr. Chairman, I think that the fact that you felt the need to call this hearing underlines the severe shortcomings of the procedures which have been governing our consideration of legislation. I agree that this bill has been very inadequately debated, but that was the decision of the majority. This precedent-setting bill, having a Federal policy dealing with some aspects of abortion, preempting what has always been a State matter, whether or not to regulate this, is to the extent that the Supreme Court allows anybody to regulate it, Federal, State, it is very much a State matter. There is an effort to try to justify this intervention into State decisionmaking in the bill, which I will return to, the phrase, "whoever in or effecting interstate or foreign commerce performs the abortion."

But not only did we make the precedent-setting decision to have a national statute limiting abortion even in States which have chosen not to limit, but we did it with no amendments allowed on the floor of the House, and only the one hour of debate.

I agree that this is a very important subject. It should get more discussion, but it shouldn't get it in a hearing room with just a few Members present; it ought to be a debate that the whole House could participate in. And that's why I continue to regret very much the decision of the majority to bring this bill to the floor under the most restrictive possible rule, a rule which allowed no amendments whatsoever and which allowed only an hour's debate, as I remember. Now, yes, it is true, you get inadequate debate when you are this restrictive, and now we will be dealing, I guess, with a motion to adopt a Senate bill, and we will again have an hour debate. And it's a procedure which will make amendment virtually impossible.

If, in fact, you are as committed, as you say, to open debate, let's have this bill on the floor in a form in which we can talk about it. But to bring this up under the most restrictive possible procedure, prohibiting any amendments and bringing it up under the minimum amount of debate that's allowed—you would have had to amend the rules of the House to give it any less debate. You couldn't do that, so you brought it up with the minimum amount of debate. Then to complain about the need to have a hearing seems to me inappropriate.

And I am particularly struck by that because one issue that will remain unexplained is this key phrase "whoever in or effecting interstate or foreign commerce knowingly performs a partial-birth abortion." We are talking here about a criminal statute. It has always been an essential element of fairness and jurisprudence that someone facing a charge under a criminal statute would have full notice of whether his or her behavior was criminal. I defy anyone to explain to me how a doctor or a woman knows that he or she is having an abortion or performing an abortion that effects interstate commerce. I suppose the easy case would be if a particular medical facility straddled State lines. But, for the rather substantial majority of cases where we do not have medical facilities straddling State lines, what does this mean? It obviously doesn't mean anything. It's not a serious phrase.

Let's be very clear. The majority wants to legislate on abortion. The majority is a little bit uncomfortable with this because it keeps talking about States' rights. Now abortion has always been something that the States could deal with if they want to within the Supreme Court's opinion. They could certainly, to the extent that anybody can deal with this, the Supreme Court has set some limits, but to the extent that this can be legislated on, the State's power is the same as the Federal. So how do you justify a Federal statute that seeks to make something illegal that States have decided to allow legal? Well, you say it only will happen if it effects interstate commerce. It's obviously a make-weight, a throw-in. And it is one that, I think, undermines the fairness of the bill even under its own terms, because, how do you know whether or not your abortion is in interstate commerce?

In the *Lopez* decision involving guns, the new Supreme Court majority said, "We're going to take a very tough view of what's interstate commerce." The fact that a gun may have been sold in one State and brought into another did not appear in *Lopez* to justify it being in interstate commerce.

So we have a very real uncertainty here, and to pass a criminal statute which tells people that you will go to prison if you have performed this type of abortion in interstate commerce, when no one can logically tell you what that means, and then to have it debated in such a restrictive fashion that you can't possibly atom-break that on the floor of the House because we had one hour before, we're going to have one hour now, no amendments are allowed, we couldn't deal with this. You complicate it.

So, I agree, this is something where there is going to be some uncertainty. This is something about which there will be confusion. But that is a self-inflicted wound by the majority because they brought this bill up in the most restrictive possible form, and it is because of that that many, many of these questions will be unanswered.

Mr. CANADY. Mr. Hyde.

Mr. HYDE. I thank the chairman for yielding.

One of my big objections to term limits is it would not permit people to be around here who've been here for a few years and have some experience. Now the gentleman complains about restricting—only an hour debate on this issue. I remember when we debated a constitutional amendment, called the equal rights amendment, under suspension. We had 20 minutes on our side to debate that, and we had to divide that 10 minutes to the pro side and 10 minutes to the con side. That was under the great, late Tip O'Neill. Ten minutes, those of us who opposed the ERA had to debate it. So this is nothing new.

As far as abortion being federalized, that was done by the Supreme Court. And those people who think abortion is a grand and great idea enjoy its being federalized. I think it was Saul Bellow, I hope it was Saul Bellow, because that's who I think it was, said, and I'm probably mangling his quote, but it's so apropos here today, "A great deal of energy can be expended in error when the need for illusion is great."

It seems to me, this debate, attenuated or not, lacks a certain candor. Taking a baby and birthing that baby almost 90 percent and then justifying, defending putting the scissors in her neck and sucking out her brains as a means of abortion ought to be beyond the pale of any civilized society. But it isn't. By God, you won't give an inch on abortion, the sacred right of abortion. And so, you determine, I guess, that that little almost-born baby is a thing, less valuable than an animal. There are organizations to protect animals, People for the Ethical Treatment of Animals, not the ethical treatment of fetuses.

So we're here trying to illegalize, illegitimate, outlaw a method of killing, exterminating an unborn child, that is cruel. It certainly is not unusual enough, I'm sorry to say. But, to defend this is to say that nothing is beyond the pale.

I thank the gentleman for yielding.

Mr. CANADY. The gentlelady from Colorado.

Mrs. SCHROEDER. I thank the chairman. I would ask unanimous consent to put my statement in the record.

I would also ask unanimous consent to put some posters up, too, because I think that this focuses on what the real issues should be in this bill.

I join the gentleman from Massachusetts in saying this is amazing. We've already had what we thought was a mock hearing, in our rapid, fast-fire movement of this bill, and now people are saying that they agree so much with the Senate that they are not even going to conference it; they're going to bring it back.

But we're having a hearing today. On what? What is the point? In the interim, we're going to take up the assault weapons ban repeal tomorrow, and this committee doesn't even have time to have a hearing on that. They're just going to bring it to the floor and go forward. So you begin to wonder. It really looks like this is a political 30-second ad generator machine.

Now, as I look at where we are today, I understand the concern of the anesthesiologists who are worried that inadvertently there was a message to women that could have gone out saying that they could not safely carry their children to term and have anesthesia. If that's the inadvertent message, we don't want that message to go out, and certainly that is not the point of what we're trying to do here.

But if you wanted to have a legitimate hearing on this bill and where it is, I think that you would have to look at, No. 1, the Ohio court decision, a 100-page decision, holding a bill very similar to this that was passed in Ohio to be unconstitutional, and, No. 2, the letter from the President to Chairman Hyde stating that he would veto this bill because it does not have a true exception for the life and health of the mother.

Mr. Chairman, I would ask unanimous consent to put that court decision and the letter to Chairman Hyde in the record at this point.

Mr. CANADY. Without objection.

[The information follows:]

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DAYTON

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

WOMEN'S MEDICAL PROFESSIONAL CORP. :

and :

MARTIN HASKELL, M.D., :

Plaintiffs, :

vs. :

GEORGE VOINOVICH, GOVERNOR, STATE OF OHIO :

and :

BETTY MONTGOMERY, ATTORNEY GENERAL, STATE OF OHIO :

and :

MATTHIAS HECK, JR., PROSECUTING ATTORNEY, MONTGOMERY COUNTY, OHIO, :

Defendants. :

Case No. C-3-95-414

JUDGE WALTER HERBERT RICE

DECISION AND ENTRY GRANTING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION (DOC. #2); DEFENDANTS, EMPLOYEES, AGENTS, SERVANTS PRELIMINARILY ENJOINED FROM ENFORCING ANY PROVISION OF HOUSE BILL 135, PENDING A FINAL DECISION ON THE MERITS; CONFERENCE CALL SET TO DETERMINE FURTHER PROCEDURES TO BE FOLLOWED IN THIS LITIGATION

Never, since the final shot of the Civil War, over a century and a quarter ago, has American society been faced with an issue so polarizing and, at the same time, so totally incapable of either rational discussion or compromise, as is the ongoing controversy, of which this case is but the latest chapter, over the legality of attempts by the State to regulate abortion--the act of voluntarily terminating a pregnancy, prior to full term.[1]

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[1] According to the Supreme Court's opinion in Roe v. Wade, 410 U.S. 113 (1973), until the last half of the nineteenth century, most states used the English common-law approach to abortion, which only criminalized abortion after the fetus "quickened," or moved in utero, which typically occurred during the sixteenth to eighteenth weeks of pregnancy. Id. at 132, 138. In the latter half of the nineteenth century, a number of states enacted statutes which criminalized abortion, at any stage of pregnancy. Id. at 139. By the end of the 1950s, most states banned all abortions except those necessary to preserve the life or health of the mother. Id.

In Roe, the Supreme Court held that a pregnant woman has a constitutional right to privacy, under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, which prevents states from proscribing abortion before viability. 410 U.S. at 147-65. Roe also established a trimester framework: during the first trimester, the State could not interfere with the woman's decision to have an abortion; during the second trimester and until viability, the State could regulate abortion in ways that were reasonably related to the mother's health; after viability, the State could proscribe abortion, except where necessary to preserve the life or health of the mother. Id. at 163-65.

In Planned Parenthood v. Casey, 112 S.Ct. 2791 (1992), the Supreme Court reaffirmed Roe's "central holding" that, prior to viability, the State could not prohibit any woman from obtaining an abortion, because of the woman's liberty interest as protected by the Fourteenth Amendment to the United States Constitution. In contrast to Roe, however, the Court placed a greater emphasis on the State's interest in potential life throughout pregnancy. Accordingly, the Court discarded the trimester framework in Roe, and allowed the State to regulate pre-viability abortions as long as the regulation did not impose an "undue burden": that is, as long as the regulation had neither "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." Id. at 2820-21.

In the few years since Casey was decided, several states have enacted regulations on pre-viability abortions, and the constitutionality of some these regulations has been challenged. See, e.g., Planned Parenthood v. Miller, 63 F.3d 1452 (8th Cir. 1995) (striking down parental notification provisions, criminal provisions, and civil penalty provisions; upholding mandatory information requirements); Jane L. v. Bangerter, 61 F.3d 1493 (10th Cir. 1995) (striking down ban on abortions after 20 weeks, fetal experimentation ban, and choice of method requirement; upholding medical emergency exception); Fargo Women's Health Org. v. Schafer, 18 F.3d 526 (8th Cir. 1994) (upholding mandatory information requirement, 24-hour waiting period, and medical emergency definition); Barnes v. Mississippi, 992 F.2d 1335 (5th Cir.) (upholding parental consent requirement and judicial bypass mechanism), cert. denied, 114 S.Ct. 468 (1993); Barnes v. Moore, 970 F.2d 12 (5th Cir.) (upholding informational requirement and 24-hour waiting period), cert. denied, 113 S.Ct. 656 (1992); Utah Women's Clinic, Inc. v. Leavitt, 844 F. Supp. 1482 (D. Utah 1994) (upholding 24-hour waiting period and medical emergency exception); Planned Parenthood v. Neely, 804 F. Supp. 1210 (D. Ariz. 1992) (striking down medical emergency definition, and definition of medical procedures with respect to an abortion).

Over the course of six days of hearings, this Court has heard testimony from a number of medical practitioners, each expert in the field in which he or she testified. This Court believes that, regardless of the personal opinions of these professionals, whether pro-choice or pro-life, each testified, not in accordance with those personal opinions, but rather on the basis of his or her medical opinion. So, too, has this Court endeavored to put aside its personal opinion on the issues herein, in order to render an opinion which it believes is mandated by the present state of the law.

This case presents a challenge to the constitutionality of House Bill 135, which was enacted by the Ohio General Assembly on August 16, 1995, and was to have become effective on November 14, 1995. After hearing two days of testimony, this Court granted a ten-day Temporary Restraining Order on November 13, 1995, which was extended for an additional ten days, and was set to expire today, on December 13, 1995. Following four additional days of testimony, the Court now issues a preliminary injunction which enjoins enforcement of the three major portions of the Act: the ban on the use of the Dilation and Extraction ("D&X") abortion procedure; the ban on the performance of post-viability abortions, and the viability testing requirement. During the effective period of this preliminary injunction, no part of House Bill 135 may be enforced, as there is no part which appears to be either constitutional, or severable, from the remainder of the Act.

This Act creates two separate bans, and a separate requirement with regard to post-viability abortions. *First*, the Act bans the use of the Dilation and Extraction ("D&X") procedure[2] in all abortions, including those performed before viability. O.R.C. § 2919.15(B). Physicians who are criminally prosecuted or sued civilly for violating this ban may assert, as an affirmative defense, that all other available abortion procedures would pose a greater risk to the health of the pregnant woman. § 2919.15(C); § 2307.51(C). *Second*, the Act bans all post-viability abortions, except where necessary to prevent the pregnant woman's death, or to avoid a serious risk of substantial and irreversible impairment to a major bodily function.[3] § 2919.17(A). For purposes of the post-viability ban only, any unborn child of at least 24 weeks is presumed to be viable.[4] § 2919.17(C). *Third*, the Act also imposes a viability testing requirement before an abortion may be performed after the 22nd week of pregnancy. § 2919.18. Unless a medical emergency exists, any physician intending to perform a post-viability abortion must meet several requirements.[5] The Act creates civil and criminal liability for violations of the D&X ban or the post-viability ban, and criminal liability for violations of the viability testing requirement.[6]

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[2] The D&X procedure is defined as:

> The termination of a human pregnancy by purposely inserting a suction device into the skull of a fetus to remove the brain. "Dilation and extraction procedure" does not include either the suction curettage procedure of abortion or the suction aspiration procedure of abortion.

O.R.C. § 2919.15(A).

[3] The determination that a post-viability abortion is necessary must be made in good faith, and in the exercise of reasonable medical judgment. O.R.C. § 2919.17(A).

[4] The gestational age is calculated from the first day of the last menstrual period of the pregnant woman. § 2919.16(B).

Plaintiff Women's Medical Professional Corporation ("WMPC") operates clinics and provides abortion services in Montgomery, Hamilton, and Summit Counties (Doc. #1, ¶5). Plaintiff Haskell, a doctor affiliated with Plaintiff WMPC, formerly performed abortions after the 24th week, but no longer does so; he uses the D&X procedure for abortions during the 21st to 24th week of gestation (Id., ¶6). On October 27, 1995, Plaintiffs filed this suit for declaratory and injunctive relief from all provisions of the Act, on their own behalf and on behalf of their patients. Plaintiffs allege that this Act imposes an undue burden on the rights of their patients to choose an abortion, and, further, that the Act's provisions are unconstitutionally vague and fail to give physicians fair warning as to what actions will incur criminal and civil liability. Accordingly, they seek to enjoin the Act as a violation of Plaintiffs' rights to privacy, liberty, and due process, as guaranteed by the Fourteenth Amendment to the United States Constitution.

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[5] The following requirements apply to post-viability abortions: (1) the physician must certify the necessity of the abortion in writing, (2) a second physician must certify the necessity of the abortion in writing, after reviewing the patient's medical records and tests, (3) the abortion must be performed in a health care facility which has access to neonatal services for premature infants, (4) the physician must choose the abortion method which provides the best opportunity for the fetus to survive, unless it would pose a significantly greater risk of death to the pregnant woman, or a serious risk of substantial and irreversible impairment to a major bodily function, and (5) a second physician must be present at the abortion to care for the unborn human. O.R.C. § 2919.17(B)(1). These conditions need not be complied with if the physician determines, in good faith and in the exercise of reasonable medical judgment, that a medical emergency exists and prevents compliance. § 2919.17(B)(2).

[6] Violation of the viability testing requirement is a fourth degree misdemeanor. O.R.C. § 2919.18(B). Violation of either the D&X ban or the post-viability ban is a fourth degree felony. § 2919.15(D), § 2919.17(D). A patient upon whom one of these procedures is performed or attempted to be performed is not criminally liable. § 2919.15(E), § 2919.17(E). She may, however, sue within one year of the procedure or attempted procedure for compensatory, punitive, and exemplary damages, as well as for costs and attorneys fees. § 2307.51(B), § 2307.52(B). Derivative claims for relief may also be brought. § 2305.11(D)(3)&(7).

I. Jurisdiction, Ripeness, Standing, Preliminary Injunction Standard

Before addressing the merits of Plaintiffs' request for a preliminary injunction, this Court must address three issues relating to its jurisdiction over this action. First, because this case involves a challenge to the constitutionality of a state statute under the United States Constitution, federal question jurisdiction is proper under 28 U.S.C. § 1331. Second, even though Plaintiff Haskell has not yet been prosecuted for violating the Act, this case is ripe for decision because a doctor facing criminal penalties for performing abortions may sue for pre-enforcement review of the relevant statute. Doe v. Bolton, 410 U.S. 179, 188 (1973).

Third, Plaintiff Haskell has the necessary standing to raise both his own rights and the rights of his patients. Because Plaintiff Haskell has asserted that he intends to continue performing the D&X procedure after this law takes effect, he is at direct risk of prosecution, and has standing to seek pre-enforcement review of this statute. Doe, 410 U.S. at 188. Given the close relationship between Plaintiff Haskell and his patients, and given the obstacles which prevent pregnant women from challenging this statute, including a desire for privacy and the imminent mootness of their claims, he may also assert third-party standing and raise the rights of his patients. Singleton v. Wulff, 428 U.S. 106 (1976) (plurality opinion) (allowing two doctors to sue for declaratory and injunctive relief from state statute taking away Medicaid funding for abortions), cited with approval in Planned Parenthood Ass'n v. Cincinnati, 822 F.2d 1390, 1396 (6th Cir. 1987). It is also noteworthy that in Planned Parenthood v. Casey, 112 S.Ct. 2791 (1992), an action for declaratory and injunctive relief from a state statute restricting the right to abortion was brought by similar plaintiffs: abortion clinics and a doctor. Based on the foregoing authority, Plaintiff Haskell has standing to bring this action, and to assert both his own rights and the rights of his patients. Although Defendants have argued that the Plaintiff must show that a particular woman will be impacted by the Act in order to have standing to raise her rights, this Court agrees with Plaintiff Haskell's argument that such a showing is unnecessary. It is sufficient that Plaintiff Haskell has alleged that he regularly has patients upon whom he performs the procedure, and that he will have such in the future.[7]

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[7] In addition, this Court notes that one such patient, Jane Doe Number 2, testified in this hearing after her abortion was performed by Dr. Haskell on November 30, 1995—two weeks after the Act was to have taken effect.

Plaintiff Haskell also has standing to challenge the provisions of the Act which ban post-viability abortions, codified at O.R.C. § 2919.17, and the viability testing requirement in O.R.C. § 2919.18. Defendants have argued that he lacks standing to challenge these provisions, because he only performs the D&X procedure up through the 24th week of pregnancy (Defendant's Memorandum in Opposition, Doc. #11, p.27, 34). The ban on post-viability abortions, however, imposes a rebuttable presumption of viability at 24 weeks, O.R.C. § 2919.17(C), which will apply to Plaintiff Haskell. If, in certain cases, he is unable to rebut the presumption of viability, the remaining provisions relating to the ban on post-viability abortions will also apply to him. In addition, Plaintiff Haskell will have to satisfy the viability testing requirement for any patients he treats who are in or beyond their twenty-second week of pregnancy. Therefore, Plaintiff Haskell also has standing to challenge these provisions of House Bill 135.

Plaintiff WMPC sues on behalf of its physicians who are employed at its various affiliated locations, and on behalf of women who receive medical services, including abortions, at these locations. This Court does not now reach the issue of whether Plaintiff WMPC has standing to bring this action, due to an inadequately developed factual record.[8] This issue need not be reached at this time, because Plaintiff Haskell's standing is sufficient to allow this action to go forward. Accordingly, the remainder of this opinion will use "Plaintiff" in the singular, in reference to Plaintiff Haskell. This Court now turns to the merits of Plaintiff's Motion for a Preliminary Injunction.

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[8] For example, although Plaintiff WMPC has asserted that it has standing because it will incur civil liability under the Act, this Court does not now have facts sufficient to conclude that Plaintiff WMPC may be civilly liable.

When considering whether a preliminary injunction is proper, this Court must consider four factors: (1) the substantial likelihood of the Plaintiff's success on the merits; (2) whether the injunction will save the Plaintiff's patients from irreparable injury; (3) whether the injunction would harm others;[9] and (4) whether the public interest would be served by issuance of the injunction. International Longshoremen's Ass'n v. Norfolk Southern Corp., 927 F.2d 900, 903 (6th Cir. 1991), cert. denied, 112 S.Ct. 63 (citing In re DeLorean Motor Co., 755 F.2d 1223, 1228 (6th Cir. 1985)). This Court need not conclude that all four factors support its decision. Chrysler Corp. v. Franklin Mint Corp., 1994 U.S. App. LEXIS 18389, at *4 (6th Cir. 1994). Rather than being "rigid and unbending requirements" that must be satisfied, these factors are intended to guide this Court's discretion in balancing the equities. In re Eagle-Picher Industries, Inc., 963 F.2d 855, 859 (6th Cir. 1992). For example, the degree of likelihood of success which is required to issue a preliminary injunction may vary according to the strength of the other factors. In re DeLorean Motor Co., 755 F.2d at 1229. This Court must make specific findings as to each of these factors, unless fewer are dispositive of the issue. International Longshoreman's Ass'n, 927 F.2d at 903.

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[9] This third prong is also construed as a "balancing of equities"; to wit, whether the harm which would be suffered by the Plaintiff if the injunction were not granted, outweighs the harm which would be suffered by the Defendant if the injunction were to be granted.

II. Plaintiff's Substantial Likelihood of Success on the Merits

Plaintiff has asserted a number of arguments attacking the constitutionality of the D&X ban, the post-viability ban, and the viability testing requirement. Many of these arguments can be divided into two categories: first, those that assert that the Act either imposes an undue burden on a woman's right to an abortion, or jeopardizes the pregnant woman's health, and is thus unconstitutional under Casey; second, those that assert that the Act is unconstitutionally vague. Before addressing these arguments, this Court will briefly set forth the relevant law to be applied to each of these categories. This Court will then consider each of the three challenged statutory provisions in turn.

A. Standards for Challenging Abortion Regulations

1. The Substantive Law

In Planned Parenthood v. Casey, a plurality of the Supreme Court held that viability marks the point at which the State's interest in protecting the potential life of the fetus outweighs the pregnant woman's liberty interest in having an abortion, subject only to a medical determination that her own life or health is at risk. 112 S.Ct. at 2816-17, 2819-2821. Before viability, states may not enact regulations which have "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion...." 112 S.Ct. at 2820. Such regulations constitute an "undue burden" on a pregnant woman's right to have an abortion, and are an unconstitutional violation of her liberty interest, as guaranteed by the Fourteenth Amendment to the United States Constitution. Id. at 2819. After viability, however, the State may regulate and proscribe abortions "except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." Id. at 2821. Therefore, whereas regulations which affect pre-viability abortions are subject to an undue burden analysis, regulations which apply only to post-viability abortions are presumptively valid, unless they have an adverse impact on the life or health of the pregnant woman.

It has been suggested that "strict scrutiny" should be applied to the medical necessity exception to the ban on post-viability abortions, codified at O.R.C. § 2919.17(A)(1).[10] In the opinion of this Court, a strict scrutiny approach would be improper in this specific situation, because it might allow a state, in some circumstances, to proscribe a post-viability abortion even where such an abortion is necessary to preserve the life or health of the mother. For example, in a situation where the mother is terminally ill, and is only expected to live for a maximum of six months following the post-viability abortion that saves her life, a state might attempt to argue that its interest in the fetus's life was actually more compelling than the mother's compelling interest in her own life, and that this interest should allow it to forbid an abortion in that circumstance.

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[10] Quite obviously, such a level of scrutiny cannot be applied to the ban itself, for Casey instructs us that a state may ban abortions after viability, unless an abortion is necessary, in the appropriate medical judgment, to preserve the life or health of the mother.

This would force courts to decide when, and under what circumstances, an unborn child's life becomes more important, and more worthy of protection, than the life of its mother. In the opinion of this Court, this inquiry is beyond the realm of legal jurisprudence, and must be left to the discretion of the individuals involved. Neither the legislature, nor the courts, has either the legal or the moral authority to balance the interests and the lives involved, and to make this decision.

Therefore, this Court holds that although a state may ban most abortions subsequent to viability, it may not take away a pregnant woman's right, as recognized in Casey, to have a post-viability abortion which is necessary to preserve her life or health. A strict scrutiny analysis could have the effect of narrowing this exception, and should not be applied. Instead, any regulation which impinges upon or narrows this exception, must be declared to be unconstitutional.

2. Standard for Reviewing Facial Challenges to Abortion Regulations

There is some dispute as to the proper showing which Plaintiff must make in order to succeed in bringing this facial challenge.[11] Before the Supreme Court's decision in *Casey*, a plaintiff bringing a facial challenge to a statute imposing restrictions on abortion faced the difficult burden of establishing "that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987), *followed by* *Rust v. Sullivan*, 500 U.S. 173, 183 (1991) (applying *Salerno* to facial challenge to regulations prohibiting facilities which receive federal funds from counseling, referring, or advocating abortion as a method of family planning); *Ohio v. Akron Center for Reproductive Health*, 497 U.S. 502, 514 (1990) (applying *Salerno* to facial challenge to judicial bypass procedure for minors seeking abortions); *cited* *in* *Webster v. Reproductive Health Services*, 492 U.S. 490, 524 (O'Connor, J., concurring) (applying *Salerno* to facial challenge to state law prohibiting use of public facilities to perform abortions except where necessary to save the mother's life). In Casey, however, the plurality employed a more relaxed standard in striking down the Pennsylvania spousal notification provision: the law was held to be invalid because "in a large fraction of the cases in which [it] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." 112 S.Ct. at 2830. Moreover, when examining the informed consent provision, the plurality specifically examined the record, and the facts contained therein, which related to the application of the challenged provision to specific persons and in specific circumstances. Id. at 2825-31. This appeared to signal a new approach to evaluating facial challenges to pre-viability abortion regulations.

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[11] The difference between challenging a statute "on its face," as in this case, or in challenging it "as applied," was recently explained by Justice Scalia:

> Statutes are ordinarily challenged ... "as applied"—that is, the plaintiff contends that application of the statute in the particular context in which he has acted, or in which he proposes to act, would be unconstitutional. The practical effect of holding a statute unconstitutional "as applied" is to prevent its future application in a similar context, but *not* to render it utterly inoperative. To achieve the latter result, the plaintiff must succeed in challenging the statute "on its face."

Ada v. Guam Society of Obstetricians & Gynecologists, 113 S.Ct. 633 (1992) (Scalia, J., dissenting from denial of *cert.*). In the instant case, Plaintiff Maskell seeks to have the entirety of House Bill 135 declared unconstitutional, and not only as it applies to his particular situation. Thus, he is bringing a facial challenge to the statute.

Since Casey, a split has developed among the Circuits as to whether the Casey approach has replaced the Salerno standard. The Third and Eighth Circuits, joined by district courts in the Seventh (Indiana) and Tenth Circuits (Utah), have concluded that Casey did replace Salerno. Planned Parenthood, Sioux Falls Clinic v. Miller, 63 F.3d 1452, 1458 (8th Cir. 1995) ("we choose to follow what the Supreme Court actually did ... and apply the undue burden test"); Casey v. Planned Parenthood, 14 F.3d 848, 863 n.21 (3rd Cir. 1994) ("the Court has... set a new standard for facial challenges to pre-viability abortion laws"); A Woman's Choice-East Side Women's Clinic v. Newman, Cause No. IP 95-1148-C H/G, at 19-20 (S.D. Ind. 1995) (memorandum opinion on motion for preliminary injunction) ("this court believes that Casey effectively displaced Salerno's application to abortion laws"); Utah Women's Clinic v. Leavitt, 844 F. Supp. 1482, 1489 (D. Utah 1994) ("to bring a facial challenge in good faith, one must reasonably believe that the statute is incapable of being applied constitutionally in a large fraction of the cases in which it is relevant."). The Fifth Circuit has disagreed, and continues to apply the Salerno standard when evaluating restrictions on abortion. Barnes v. Moore, 970 F.2d 12, 14 n.2 (5th Cir. 1992) ("we do not interpret Casey as having overruled, sub silentio, longstanding Supreme Court precedent governing challenges to the facial constitutionality of statutes").

The Supreme Court, itself, appears to be split on this issue. Compare Fargo Women' Health Org. v. Schafer, 113 S.Ct. 1668 (1993) (O'Connor, concurring with denial of application for stay and injunction) (stating that the Casey approach should be followed by lower courts), with Ada v. Guam Society of Obstetricians and Gynecologists, 113 S.Ct. 633 (1992) (Scalia, dissenting from denial of petition for writ of certiorari) (stating that Court did not change the Salerno standard in Casey).

Not surprisingly, whereas Plaintiff has urged this Court to adopt the Casey approach, Defendants have vigorously argued that the Salerno standard should be employed. Because the Sixth Circuit is silent on the issue of whether Salerno should apply to pre-viability abortion regulations, it is a matter of first impression in this Circuit.

This Court concludes that for purposes of evaluating the ban on the D&X procedure, which is used in the weeks preceding viability, this Court will follow the approach actually undertaken in Casey, and employed by courts in the Third, Seventh, Eighth, and Tenth Circuits, and ask whether, "in a large fraction of the cases in which [the ban] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." This Court makes this decision for two reasons. First, because Casey did not require that every married woman be subject to physical abuse in striking down the spousal notification requirement, the plaintiffs in that case did not have to show that "no set of circumstances exist under which the law would be invalid" in order to successfully challenge it. Second, it seems that it would be impossible, as a practical matter, to evaluate whether a regulation will create an undue burden on the right to an abortion, without examining specific facts in the record, and evaluating the likely impact that a regulation will have on the specific group of women who are affected by it. For these reasons, this Court declines to apply Salerno to the challenged pre-viability regulations in this case.

Although this Court has concluded that it will not apply Salerno to the pre-viability regulations in House Bill 135, the issue of whether Salerno should apply to the post-viability regulations in House Bill 135 is a separate issue.

For purposes of evaluating the ban on post-viability abortions, therefore, this Court must likewise consider whether it is bound to apply the more restrictive Salerno standard.[12]

Whether the Salerno standard for facial challenges should apply to post-viability regulations appears to be an issue of first impression before this, or any, Court. Casey is not dispositive, because the approach in that case is specifically designed to evaluate whether a law restricting access to pre-viability abortions would impose an "undue burden" on a large fraction of the relevant population; it does not evaluate whether a law restricting access to post-viability abortions is invalid simply because it may jeopardize the life or health of a few (or many) pregnant women who need such an abortion. Indeed, none of the cases cited above which followed the new Casey approach involved restrictions on post-viability abortions. Thus, this appears to be an issue of first impression in this, or any, Court.

After careful consideration of the interests involved, this Court concludes that the Salerno requirement that the plaintiff must show that "no set of circumstances exists under which the law would be valid," should not apply to facial challenges to post-viability abortion regulations which may unconstitutionally threaten the life or health of even a few pregnant women. The Court so holds for three reasons. First, the cases which have applied *Salerno* have not involved laws which threaten to inflict, unconstitutionally, such severe and irreparable harm.[13] Second, because the Supreme Court signalled in *Casey* that an unconstitutional infringement of the liberty interests of some, but not all, pregnant women, is sufficient to justify application of a lesser standard where a pre-viability abortion is concerned, there is no reason why the Court would not similarly apply a lesser standard where a law threatens to deprive some, but not all, pregnant women of their greater constitutional interest in their own life and health. Finally, and most importantly, it would be unconscionable to hold that a pregnant woman--or her estate--may not challenge a post-viability regulation until *after* she is unconstitutionally deprived of her life or health. Therefore, this Court will allow Plaintiff to facially challenge this post-viability ban, even though he has not shown that "no set of circumstances" exists under which the ban would be valid.

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[12] Defendants have argued, for example, that the testimony given by Jane Doe Number One and Jane Doe Number Two--both of whom would have been adversely affected by this ban on post-viability abortions--should be disregarded by this Court, because Salerno requires that the law be unconstitutional in all of its applications, rather than in a few or many situations. Because this is a facial challenge, Defendants argue, such testimony as to how the law may affect specific individuals is irrelevant.

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[13] In *Rust*, the Court applied *Salerno* to a facial challenge to regulations which restricted the ability of facilities receiving Title X funding to counsel, make referrals, or advocate, abortion. 500 U.S. at 183. In *Akron Center for Reproductive Health*, plaintiffs brought a facial challenge to a parental notification statute; in considering the judicial bypass procedure, the Court applied *Salerno*, rejecting arguments that the procedure's time requirements might be construed as "business days" instead of "calender days," and reasoning that the statute should not be invalidated "based on a worst-case analysis that may never occur." 502 U.S. at 514. Finally, in *Webster*, Justice O'Connor stated that *Salerno* should apply to a Missouri provision that prohibited the use of public facilities to perform abortions not necessary to save the life of the mother. 490 U.S. at 523.

B. Standard for Vagueness Challenges

In addition to arguing that this Act is unconstitutional under Casey, Plaintiff argues that the Act is unconstitutionally vague. When determining whether a statute or regulation is sufficiently vague so as to violate due process, there are several relevant considerations. A statute or regulation may be vague if it fails to give fair warning as to what conduct is prohibited. Grayned v. City of Rockford, 408 U.S. 104, 108 (1972) ("we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly"), cited in Fleming v. United States Dept. of Agriculture, 713 F.2d 179, 184 (6th Cir. 1983). A statute or regulation may also be vague if it is subject to arbitrary and discriminatory enforcement, due to a failure to provide explicit standards for those who apply the law. Id. Finally, the lack of a mens rea requirement in a statute which imposes criminal liability may indicate that the statute is unconstitutionally vague. Colautti v. Franklin, 439 U.S. 379, 395 (1979) ("Because of the absence of a scienter requirement in the provision directing the physician to determine whether the fetus is or may be viable, the statute is little more than 'a trap for those who act in good faith.'").

A vague law is especially problematic in two situations. First, its potential to cause citizens to "'steer far wider of the unlawful zone' ... than if the boundaries of the forbidden areas were clearly marked," Id. (quoting Baggett v. Bullitt, 377 U.S. 360, 372 (1964)), is of particular concern where the exercise of constitutionally protected rights may be inhibited or "chilled." Colautti v. Franklin, 439 U.S. 379, 391 (1979) (applying to the right to an abortion); Baggett, 377 U.S. at 372 (applying to First Amendment rights). Second, a vague law which provides for criminal penalties is troubling because of the severe consequences which may result from violating the law. Hoffman Estates v. The Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99 (1982). When determining whether a law is void for vagueness, this Court must examine the challenged law in light of all of the above considerations.

This Court now turns to Plaintiff's arguments challenging the constitutionality of the D&X ban, the post-viability ban, and the viability testing requirement, for purposes of gauging whether the likelihood of Plaintiff's success on the merits of these arguments is substantial.

C. Ban on Use of the D&X Procedure

1. Vagueness of the Definition of D&X

House Bill 135 bans the performance or attempted performance of any abortion, pre-viability or post-viability, by use of the Dilation and Extraction ("D&X") procedure, which is defined as follows:

> [T]he termination of a human pregnancy by purposely inserting a suction device into the skull of a fetus to remove the brain. 'Dilation and extraction procedure' does not include either the suction

> curettage procedure of abortion or the suction aspiration procedure of abortion.

O.R.C. § 2919.15(A). Plaintiff argues that this definition is unconstitutionally vague, because it does not adequately distinguish the D&X procedure from a different procedure known as the Dilation and Evacuation ("D&E") procedure. Plaintiff further argues that this vagueness will chill physicians from performing abortions by use of the D&E method, which is the most common method used in the early to mid-second trimester. Defendants dispute this, arguing that the definition does not include or describe the D&E procedure, and so is not vague; further, Defendants argue that the D&E procedure is included in the definition of suction curettage, and so is excepted from the ban.

In order to address this vagueness argument, it is necessary to define and describe the various methods of abortion, based on the testimony in this case. When the procedures are described in detail, it becomes apparent that the statutory definition of the Dilation and Extraction procedure could be construed to include the more widespread Dilation and Evacuation ("D&E") procedure. It also becomes apparent that the D&E method is not included in any definition of suction curettage: although a D&E procedure does include suction curettage, it also includes additional steps, such as dismemberment, and additional instruments, such as forceps. Furthermore, suction curettage is a first-trimester procedure, whereas D&E is a second-trimester procedure. Accordingly, Plaintiff has demonstrated a substantial likelihood of success of showing that the definition of a D&X procedure is unconstitutionally vague.

a. suction curettage/aspiration

Suction curettage and suction aspiration (also known as vacuum aspiration) are common methods of first-trimester abortions, and the terms are used interchangeably (Tr., 12/6, at 13, 115).[14] In a suction curettage procedure, the doctor mechanically dilates the opening to the uterus by the use of metal rods, inserts a vacuum apparatus into the uterus, and removes the products of conception by the use of negative suction (Tr., 12/5, at 33). There is no need to dilate the patient's carvix in the days before the procedure is performed (Id.). Suction curettage/aspiration can sometimes be performed up to the 15th week of pregnancy, but is typically a first-trimester procedure (Id.). Approximately ninety-five percent of the abortions which are performed in this country are performed during the first fifteen weeks of pregnancy[15] (Tr., 12/6, at 13).

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[14] The transcripts of the hearing testimony are, for the most part, paginated separately for each day of testimony. Therefore, when referring to transcript testmony throughout this opinion, this Court will indicate the date of the transcript, as well as the page on which the specific reference may be found.

[15] The testimony indicates that some women who seek abortions in their second trimester are victims of rape or incest, and may have been psychologically unable to face their pregnancies at an earlier time (Tr., 11/8, at 27). Other women who seek abortions in the second trimester do so because it is only then that they discover that their fetus has developed severe anomalies, i.e., physical defects that call into question the ability of the fetus, once carried to term, to survive (Tr., 12/5, at 103-08).

b. Dilation & Evacuation (D&E)

In the second trimester, the fetus becomes too large to remove by use of suction curettage (Tr., 12/5, at 33-34). At that point, the most common abortion method is a Dilation and Evacuation (D&E) procedure; indeed, it is the only procedure which can be used from the thirteenth to sixteenth weeks of pregnancy (Tr., 11/8, at 51). Instead of using metal rods to dilate the cervix over a short period of time, the doctor inserts laminaria into the cervix during the one-to-two day period prior to the procedure, in order to slowly dilate the cervix. Then, a suction curette with a larger diameter is placed through the cervix, and the doctor removes some, or all, of the fetal tissue.

Frequently, however, the torso and the head cannot be removed in this manner (Tr., 12/5, at 35). The procedure typically results, therefore, in a dismemberment of the fetus, beginning with the extremities. This dismemberment is accomplished both by use of the suction curettage, and by the use of forceps (Id.).

Removing the head of the fetus from the uterus is typically the most difficult part of the D&E procedure, in part because the head is often too large to fit through the partially dilated cervix. It is important to remove the head as quickly as possible, because fetal neurologic tissue can negatively affect the mother's ability to clot, and lead to greater bleeding (Tr., 12/6, at 32). Physicians have developed different methods of decompressing the head, in order to remove it.

Dr. Anthony Levatino testified that when he performed D&E abortions, he preferred to grasp the fetal head with a clamp, crush it, and remove it in pieces along with the skull contents (Tr., 12/7, at 190). Because he decompressed the skull by crushing it, he found it unnecessary to decompress the skull by purposely inserting a suction device into the skull and removing some of its contents (Id. at 192).

Dr. Paula Hillard testified that when the skull is too large to remove intact, she grasps the skull and suctions out its contents with a cannula--which may enter the skull--in order to decompress it and facilitate its removal (Tr., 11/8, at 77). She has never performed the procedure utilized by Dr. Haskell (Id. at 49).

Dr. Doe Number One testified that because the use of forceps can cause trauma to the mother's uterus, his preference is to collapse the head by the use of suction, prior to its removal. By making a small incision at the base of the skull and inserting a suction device into the brain--while the head is still within the uterus, and no longer attached to the body--he can collapse the head and easily remove it, without the use of forceps (Tr., 12/5, at 43). This method decreases injury to the cervix and uterus, and reduces operating room time, blood loss, and anesthesia time (Id. at 44). Dr. Doe describes his procedure as a D&E, and collapses the head by the use of suction even in procedures performed from 15 to 18 weeks. Although he does not always collapse the head in this fashion, Dr. Doe Number One testified that the two procedures--D&E with collapse, and D&E without collapse--are on a continuum (Id. at 72). He has never performed the procedure utilized by Dr. Haskell (Id. at 84).

Dr. Mary Campbell has not performed second-trimester abortions, but has read about and observed various second-trimester methods, in preparation for setting up a second-trimester practice at her clinic. In describing the D&E procedure, she testified that the fetal skull is generally not intact following dismemberment of the body--the jaw is often removed with the neck--and "the edges of the fetal skull are sharp enough to lacerate the maternal uterine [blood] vessels..." (Tr., 12/6, at 35). The goal is therefore to place the suction cannula into the skull in order to remove its contents and make it smaller, thereby allowing it to be removed intact, in order to minimize lacerations (Id. at 33). In addition, removing the head intact is advantageous because it ensures that no parts of the skull are left behind in the woman's uterus (Id. at 35).

Dr. Harlan Giles, who performs D&E abortions up to the twentieth week of pregnancy, testified that he had never seen an instance in which the fetal head was too large to be removed without being crushed or somehow decompressed, but he admitted that such an occurrence was possible (Tr., 11/13, at 269-70; Tr., 12/8, at 41).

The D&E procedure appears to be preferable to other available procedures before the twentieth week; at thirteen to sixteen weeks, it is the only available procedure. The main alternative to a D&E procedure after sixteen weeks is an induction or instillation method, which involves either the injection of saline, urea, or prostaglandins into the amniotic cavity, or, the insertion of vaginal prostaglandin suppositories. These procedures result in labor, and are further described below. The D&E procedure appears to be less painful for the mother than induction procedures, because it does not require labor, and because the cervix is dilated slowly with laminaria rather than being dilated more forcefully by uterine contractions. In addition, the D&E procedure takes less time, generally between ten and twenty minutes, as opposed to twelve to thirty-six hours. Because the uterus is not under pressure over a long period of time, there is less of a risk of forcing fluids or fetal proteins into the maternal circulation (Tr., 12/6, at 31). Finally, there is a reduced risk of retained products of conception, infection, hemorrhage, and cervical injury (Id. at 39).

Although the D&E procedure appears to have a lower rate of complications than other methods of abortion in the early to mid-second trimester, it can be equally risky at later periods, when the fetus is larger. One serious complication of later D&Es is caused by the use of forceps, which results in uterine and cervical injuries, and increased blood loss (Tr., 12/5, at 41).

C. Dilation and Extraction (D&X)

In this section, the Court will describe Dr. Haskell's specific method of abortion, which has been described by various parties as either an "intact D&E," a "brain suction procedure," or a "Dilation and Extraction" procedure. It is typically used late in the second trimester, from twenty to twenty-four weeks.

Plaintiff Haskell described his procedure in a paper presented at the National Abortion Federation Conference in 1992 (Defendant's Exhibit A). The following description is taken from that paper.

On the first and second days of the procedure, Dr. Haskell inserts dilators into the patient's cervix. On the third day, the dilators are removed and the patient's membranes are ruptured.[16] Then, with the guidance of ultrasound, Haskell inserts forceps into the uterus, grasps a lower extremity, and pulls it into the vagina. With his fingers, Haskell then delivers the other lower extremity, the torso, shoulders, and the upper extremities. The skull, which is too big to be delivered, lodges in the internal cervical os.[17] Haskell uses his fingers to push the anterior cervical lip out of the way, then presses a pair of scissors against the base of the fetal skull. He then forces the scissors into the base of the skull, spreads them to enlarge the opening, removes the scissors, inserts a suction catheter, and evacuates the skull contents. With the head decompressed, he then removes the fetus completely from the patient.

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[16] Defendants pointed out that, in the videotape in which Dr. Haskell demonstrates the procedure (Defendant's Exhibit R), the patient's membranes had ruptured (her "water had broken") prior to the procedure, on the very first day. Although this fact might be relevant if this were a medical malpractice action brought by that particular patient, it is not relevant to the issue of whether the D&X procedure is generally safe for the mother's health.

[17] Although Dr. Haskell does not state in his paper that he cuts the umbilical cord prior to penetrating the base of the skull with scissors, he testified that he routinely cuts the cord, and he did so on the videotape which demonstrates this procedure (Defendant's Exhibit R). Further, although the Court notes that it generally takes eight to ten

The primary distinction between this D&X procedure and the D&E procedure previously described appears to be that, whereas the D&E procedure results in dismemberment and piece-by-piece removal of the fetus from the uterus--and, possibly, in removal of portions of the skull contents by the use of suction after the skull is crushed with forceps or otherwise invaded, and before the head is placed next to the opening to the uterus--the D&X procedure results in a fetus which is removed basically intact except for portions of the skull contents, which are suctioned out after the head is placed next to the opening to the uterus (and after the rest of the fetus is removed from the uterus), and before the fetus is fully removed from the mother's body.[18] The hallmark of the D&X procedure, therefore, is that the fetus is removed intact, rather than being dismembered prior to removal, as is done in a D&E procedure. In both procedures, the head usually must be

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minutes for the fetus to die, following the cutting of the umbilical cord, and that, on the videotape, Haskell waited only thirty seconds from the time he cut the cord to the time he inserted the scissors, this Court also notes that the fetus in the videotape appeared to be dead at the beginning of the procedure.

[18] If the skull could not be decompressed by suctioning out part of the contents, and yet was too big to pass through the cervix, it apparently would have to be crushed in order to remove it.

decompressed, either by crushing the skull, or by invading the skull and suctioning out its contents. In the D&X procedure, the suctioning is purposeful; in a D&E procedure, the suction may either be purposeful, or, given the inability to clearly see the fetus, even with ultrasound, and the consequent difficulty of knowing whether the surgical instrument is in, or simply near, the skull, it may be accidental.

The testimony indicates that the D&X procedure may be considered to be a variant of the D&E technique.[19] Indeed, doctors who use the procedure may not know which procedure they will perform until they encounter particular surgical variables and circumstances after they begin the procedure to terminate the pregnancy.[20] The doctor may intend to do a D&X in cases where the patient has requested an intact fetus for purposes of genetic testing, or, perhaps, where a patient has a history of Cesarean sections and a uterine scar, and thus is more vulnerable to uterine injury (Tr., 12/7, at 89).

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[19] The testimony indicates that each physician's surgical procedures may differ from similar procedures used by other physicians (Tr., 12/6, at 103). Indeed, physicians experiment with and develop their own variants of surgical techniques, and then use them, even if those variants are not specifically approved in a peer review journal (Id. at 104).

In this case, Dr. John Doe Number One testified that he developed a procedure which is similar to Haskell's D&X procedure for use in his D&E procedures at fifteen to eighteen weeks: after the extremities of the fetus are dismembered and removed, he collapses the head by making an incision and then using suction to decompress the skull, instead of crushing it with forceps, so that he can remove the skull intact (Tr., 12/5, at 42-44). Dr. John Doe Number Two, who uses Haskell's D&X procedure in situations where an intact fetus is requested, or if the fetus is breech (feet first), testified that he considers the D&X procedure to be a modification of the D&E procedure (Tr., 12/6, at 47-48).

[20] Dr. Doe Number Two testified, for example, that he uses the D&X procedure in the specific circumstance when the fetus is "double footling breech" and comes out feet first, resulting in a trapped head. At that point, he has "no room to work" because the head is trapped in the lower uterine segment, and must try to finish the procedure as quickly as possible to lower the risks to the mother. In that circumstance, the D&X procedure is the safest and fastest method. If he were prohibited from suctioning out the skull contents to decompress the head, he would have to dismember the head from the body, push the detached head back up into the uterus, crush the skull with the appropriate instruments, and then remove it in pieces (Tr., 12/7, at 76).

Based on the testimony of various physicians, this Court further finds that in both the D&E and the D&X procedures, a suction device may be purposely inserted into the skull in order to remove the skull contents, to accomplish the goal of decompressing the fetal head, thereby facilitating its removal from the woman's body. Because the statutory definition of the prohibited "Dilation and Extraction Procedure" thereby appears to encompass the purportedly allowable D&E procedure as well, Plaintiff has demonstrated a substantial likelihood of success of showing that this definition is unconstitutionally vague, as it does not provide physicians with fair warning as to what conduct is permitted, and as to what conduct will expose them to criminal and civil liability.[21]

2. Constitutionality of Banning the Specific Abortion Procedure at Issue

As far as this Court is aware, only one case has considered the propriety of a ban on a specific abortion procedure. In *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52 (1976), the Supreme Court struck down a ban on the second-trimester abortion method of saline amniocentisis. The Court reasoned that, because the method was commonly used and was safer than other available methods, it failed to serve the stated purpose of protecting maternal health. The Court concluded that, given that there were no safe, available alternatives to the banned method, the ban was "an unreasonable or arbitrary regulation designed to inhibit, and having the effect of inhibiting, the vast majority" of second trimester abortions. Accordingly the ban was held to be unconstitutional. Id. at 75-79.

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[21] In addition, this Court notes that House Bill 135 bans not only the performance of D&X abortions, but also the *attempted* performance of D&X abortions. Given this Court's finding that the D&X procedure is on a continuum with the D&E procedure, this phrase adds confusion as to when a doctor, who is performing a D&E abortion, *attempts* to perform a D&X, and thus incurs criminal and civil liability.

The reasoning in Danforth suggests that a state may act to prohibit a method of abortion, if there are safe and available alternatives. This reading comports with Casey, which dictates that if a ban on a specific method were to place a substantial obstacle in the path of a woman seeking a pre-viability abortion--for example, if there were no safe and available alternative method of abortion--the ban would be an undue burden and therefore unconstitutional. The issue before this Court, therefore, is whether, in Ohio, there are safe and available alternatives to the D&X procedure, which is typically performed during the twentieth to twenty-fourth weeks of pregnancy, such that there would be no undue burden if the procedure were banned.

a. D&E Procedure

Due to the larger size of the fetus in the mid to late-second trimester, when the fetus is not necessarily viable, the D&E is no longer the procedure of choice to perform an abortion.[22] Therefore, in considering the safest method of abortion at this stage of pregnancy, this Court will compare the D&X procedure--which is typically performed from the twentieth to the twenty-fourth weeks of pregnancy--to other available procedures.

b. Instillation/Induction Procedures

The main alternative to the D&X procedure, in the late second trimester, is the use of an induction method of abortion. Induction methods are also known as "instillation" methods. In one type of induction method, the physician injects some substance--typically saline, or a combination of a prostaglandin and urea--into the amniotic cavity of the woman. In another type, the physician places prostaglandin suppositories into the patient's vagina. In both cases, the end result is labor: the substances cause the uterus to contract, resulting in the eventual expulsion of the fetus. This labor typically lasts between twelve and twenty-four hours (Tr., 12/6, at 25), but may last as long as thirty-six hours (Id. at 118).

The evidence suggests that induction methods were more frequently used in the 1970s, when the D&E procedure was just being developed. Also, induction procedures are more often used by less skilled physicians (Id. at 22). Finally, they must be performed in a hospital environment, and so cannot be done on an outpatient basis.

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[22] Additional obstacles to performing a D&E after the twenty-second week of pregnancy include: the presentation of the fetus, in which the spine is oriented toward the cervix, and the toughness of the fetal tissues; both of these factors make it more difficult to dismember the fetus (Tr., 11/8, at 177). Because the operating time is thereby increased, this can cause heavy blood loss (Id. at 178).

There appear to be two advantages which induction methods have over the D&E procedure: they require less skill to perform, and they do not involve the placement of any sharp instruments into the uterus (Id. at 29).

One obvious disadvantage of the induction method is that it results in labor, with all of its potential complications. These may include: fear, lack of control, mild to severe abdominal pain, nausea, and diarrhea, and extreme discomfort, over a lengthy period of time. The substances used, especially saline, may result in mild side effects--vomiting, diarrhea, and high fever--or in severe maternal complications. The fluids which are introduced may be forced into the maternal circulation, leading either to amniotic fluid embolus, which is generally fatal, or to disseminated intravascular coagulation (DIC), in which the clotting factors in the blood are used up, and bleeding cannot be stopped. Induction methods can also thin out the lower uterus to the point that the fetus comes through the uterine wall instead of through the vagina (Tr., 12/6, at 25-26). In addition, induction methods cannot be performed on women who have an active pelvic infection, or who are carrying dead fetuses (Id. at 26), and probably should not be performed on women who had previously had Cesarean sections, given the possibility of rupturing the uterine scar (Id. at 28). Finally, induction methods may be ineffective in cases where the fetus is lying with its head on one side and its feet on the other, because there is no pressure against the cervix (Id. at 27), and the fetus will not be expelled from the uterus.

c. Hysterectomy/Hysterotomy

Another alternative to the D&X is a hysterotomy, which is essentially a Cesarean section performed before term, although it is potentially more dangerous because the uterus is thicker than it is at the end of term, and the incision causes more bleeding and may make future pregnancies more difficult. A more extreme alternative is a hysterectomy, which removes the uterus completely. Both of these methods entail the risks associated with major surgical procedures, and are rarely used today.

d. D&X Procedure

Before discussing the apparent benefits and risks of the D&X procedure, it is necessary to address Defendant's arguments that the procedure has no measurable benefits, for the reason that no peer review journal has published any studies measuring these benefits. The Court acknowledges that if there were a statistical study, published in a peer review journal, which demonstrated the benefits of the D&X procedure, this would make the asserted benefits more credible. Nevertheless, the lack of a study in a peer review journal does not, *ipso facto*, mean that there are no benefits, or no risks. Indeed, in this situation, there are a number of factors which help to explain the lack of such a statistical study.

First, the D&X procedure is relatively new--it apparently was first described in 1992--and it will take time for other practitioners to begin using and evaluating the procedure. Second, given the security concerns which must be considered by doctors who perform abortions, physicians who use the D&X procedure may be understandably reluctant to publicly acknowledge that they use this procedure, and may be even more reluctant to participate in a study and publish the results. Finally, as was testified to by Dr. Mary Campbell, funding for studies of abortion methods was cut drastically in the early 1980s, and there have been no large-scale abortion studies since that time (Tr., 12/6, at 74, 76). Given these obstacles to performing and publishing statistically valid studies on new abortion methods, this Court is not persuaded that the absence of a study on D&X abortions in the medical literature means that the procedure has no benefits.[23]

Dr. George Goler, the Ohio Section Chief of the American College of Obstetricians and Gynecologists, testified that he views Dr. Haskell's procedure as an improvement over the traditional D&E procedure, because it causes less trauma to the maternal tissues (by avoiding the break up of bones, and the possible laceration caused by their raw edges), less blood loss, and results in an intact fetus that can be studied for genetic reasons (Tr., 12/6, at 126). Dr. Haynes Robinson, a pathologist and geneticist, testified that it is sometimes desirable to obtain an intact fetus in order to confirm the presence of fetal anomalies, and to predict their likely recurrence in future pregnancies (Tr., 12/5, at 118). Although an intact fetus can be obtained following an induction or instillation procedure--and such a method might be preferable where the brain needs to be studied intact--the use of various substances to induce labor can cause autolysis, or the breaking down of tissue, which may make the fetal tissue less useful for such studies (Tr., 12/6, at 34). A further advantage over induction or instillation procedures is that the D&X procedure takes far less time--ten to twenty minutes--than the twelve to thirty-six hours in which a woman must be in labor following an induction or instillation procedure.[24]

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[23] In addition, and for similar reasoning, this Court is unpersuaded by the Defendant's argument that the D&X procedure is not within the accepted medical standards. This is a new, controversial procedure. As Dr. Goler testified: "I don't think enough people know about it to really say its within the accepted standards of practice. I think, as it gets to be better known and the results [are] published, it will be." (Tr., 12/6, at 133-34). Given the recent development of the D&X procedure, the fact that no publication has concluded, to date, that it is within acceptable medical standards, is not dispositive.

Plaintiff Haskell testified that, in approximately 1,000 D&E procedures performed after the twentieth week of pregnancy, two patients had serious complications (Tr., 11/8, at 149). In approximately 1,000 D&X procedures performed after the twentieth week of pregnancy, there were no serious complications (Id. at 150-51). Although this is anecdotal, not statistical, evidence, this Court finds that it is both uncontradicted and plausible.

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[24] This Court rejects Defendant's claim that the D&X procedure takes longer, because it requires the insertion of laminaria one or two days before the procedure. Dr. Doe Number Two testified that the insertion of laminaria does not impair the woman's ability to function in any way, nor does it cause major discomfort, although it may cause some cramping. This does not compare to the more traumatic experience of going through labor.

Dr. Levatino, who has performed D&E but not D&X abortions, predicted that the D&X procedure would have greater complications than the induction methods, because there is an increased possibility of perforating the patient's uterus when the abortion is performed in the late second trimester (Tr., 12/7, at 198, 205). This testimony appears, however, to have been based less on his analysis of the specific procedure then on his estimate of the risks of performing late-term D&E abortions, generally. As noted earlier, the D&E procedure can be risky in the late-second trimester, because the fetus is larger and more difficult to dismember, and the use of forceps in the uterus becomes more dangerous. The D&X procedure mitigates this risk by delivering the fetus intact--except for a decompression of the head after it has been placed next to the opening to the uterus--and thus would not appear to bear an increased risk of uterine perforation. Although forceps are still used, their use appears to be minimized.

Dr. Giles testified that the procedure is not new, but is rather a resurrection of an obstetric method discarded in the 1960s, which was used to deliver dead fetuses, and known as craniotomy (Tr., 12/8, at 18-23). His criticisms of the D&X

procedure on this ground are not persuasive. First, the reason for the abandonment of the craniotomy procedure--which required the use of sharp instruments, and caused uterine lacerations and perforations--does not appear to be relevant to the D&X procedure, which reduces the risk of uterine lacerations (in comparison to the D&E procedure) by delivering all but the head of the fetus intact, which is then decompressed by the use of scissors and suction. Second, unlike the situation in the 1960s, ultrasound can now be utilized to help to avoid injury when sharp instruments are introduced into the uterus.

Finally, in regard to the availability of the D&X procedure, it can be performed on an outpatient basis, and does not require hospitalization. Although the procedure requires three separate visits to the clinic, the insertion of laminaria on days one and two takes less than an hour (Tr., 12/5, at 22), and the D&X procedure itself, which is performed on the third day, requires a total time of less than two hours (Id.). At least three doctors in Ohio perform some variation of the D&X procedure: Plaintiff Haskell (Tr., 11/8, at 109-10); Dr. John Doe Number One (Tr., 12/5, at 43); and Dr. John Doe Number Two (Tr., 12/7, at 47-48).

e. Conclusion

After viewing all of the evidence, and hearing all of the testimony, this Court finds that use of the D&X procedure in the late second trimester appears to pose less of a risk to maternal health than does the D&E procedure, because it is less invasive--that is, it does not require sharp instruments to be inserted into the uterus with the same frequency or extent--and does not pose the same degree of risk of uterine and cervical lacerations, due to the reduced use of forceps in the uterus, and due to the removal of any need to crush the skull and remove it in pieces, which can injure maternal tissue.

This Court also finds that the D&X procedure appears to pose less of a risk to maternal health than the use of induction procedures, which require the woman to go through labor, pose additional risks resulting from the injection of fluids into the mother, and cannot be used for every woman needing an abortion.

Finally, the Court finds that the D&X procedure appears to pose less of a risk to maternal health than either a hysterotomy or a hysterectomy, both of which are major, traumatic surgeries.

Because the D&X procedure appears to have the potential of being a safer procedure than all other available abortion procedures, this Court holds that the Plaintiff has demonstrated a substantial likelihood of success of showing that the state is not constitutionally permitted to ban the procedure. If this abortion procedure, which appears to pose less of a risk to maternal health than any other alternative, were banned, and women were forced to use riskier and more deleterious abortion procedures, the ban could have the effect of placing a substantial obstacle in the path of women seeking pre-viability abortions, which would be an undue burden and thus unconstitutional under Casey.

Even if induction procedures were as safe as the D&X procedure--and this Court does not find, on the evidence, that they are as safe--the requirement that a pregnant woman be hospitalized in order to undergo an induction procedure may also have a negative impact on the practical availability of abortions for women seeking pre-viability abortions. First, hospitals may refuse to allow induction procedures on an elective basis,[25] including those situations in which a woman wishes to abort a fetus with severe anomalies. Second, it may be psychologically daunting to undergo the induction procedure in the hospital environment.[26] These practical problems may discourage women in their second trimester from exercising their right of seeking elective, pre-viability abortions, or make it practically impossible to do so, thereby amounting to an undue burden on the right to seek a pre-viability abortion. In contrast, the D&X procedure can be performed on an outpatient basis within a much shorter period of time, and is not limited by either of these practical problems.

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[25] For example, Miami Valley Hospital, in Dayton, Ohio, only permits therapeutic abortions, and does not allow their performance on an elective basis (Defendant's Exhibit F). Dr. George Goler, the Ohio Section Chief of the American College of Obstetricians and Gynecologists, also testified that "it's gotten to the point now where many of the hospitals do not have facilities" to perform abortions by use of induction methods (Tr., 12/6 at 118). Although Dr. Harlan Giles, a Pennsylvania physician, testified that it was his opinion that several Ohio facilities allowed the performance of elective abortions (Tr., 11/13, at 237), this Court is more inclined to rely on the testimony of Dr. Goler, who practices in Ohio, and whose testimony was specifically directed toward second-trimester abortions. This Court concludes that the preponderance of the evidence is that few Ohio hospitals allow non-therapeutic, second-trimester abortions.

[26] Dr. Doe Number One, who used to perform induction procedures but now performs a version of the D&X procedure, testified that hospitals and hospital personnel view induction procedures as a "second-class procedure" performed on "second-class patients," and that the problem is exacerbated by the practice of locating the woman obtaining the abortion in close proximity to women giving birth (Tr., 12/5, at 37-38). Dr. Mary Campbell also testified that it's depressing for the patient to undergo an abortion procedure in the labor and delivery area of a hospital: "These are families often with wanted pregnancies gone awry who in the course of their time in the hospital ... get to hear several other families through closed doors ... shouting rather happily ... it's a boy or it's a girl." (Tr., 12/6, at 28-29).

For both of these reasons--because the D&X procedure appears to be the safest method of terminating a pregnancy in the late second trimester, and because the D&X procedure is more available than induction methods, which require the woman to be hospitalized--this Court holds that Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on the D&X procedure is unconstitutional under *Danforth* and *Casey*.[27]

3. Legitimacy of the State's Asserted Interest in Banning the D&X Procedure

Next, this Court turns to the state's asserted interest in enacting the ban on the D&X procedure, and to the constitutional legitimacy of that interest. The Ohio General

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[27] Defendants have argued that the affirmative defense, codified at O.R.C. § 2919.15(C), saves the ban from being an undue burden. Under the affirmative defense, if a physician who is prosecuted for performing a D&X procedure can present *prima facie* evidence that all other procedures would have posed a greater risk to the mother's health, then the prosecutor has the burden of proving, beyond a reasonable doubt, that at least one other abortion method would not have posed a greater risk to the mother's health.

Defendants' argument is unpersuasive, for two reasons. First, the certainty of arrest and prosecution is certain to chill physicians from performing the D&X procedure, even where it is the least risky method of abortion. Second, even if there were no chilling effect, the challenged law restricts the availability of D&X procedures to situations where it is obviously and irrefutably the safest method. Given this Court's findings that the D&X procedure may be safer and more available than other methods of abortion, this would still amount to an undue burden.

Assembly declared that its intent in banning the D&X procedure was: "to prevent the unnecessary use of a specific procedure used in performing an abortion. This intent is based on a state interest in preventing unnecessary cruelty to the human fetus." House Bill 135, Sec. 3 (emphasis added).

In Casey, the Supreme Court recognized two specific interests which the state has in regulating abortions prior to viability. First, "to promote the State's profound interest in potential life throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and [these] will not be invalidated as long as their purpose is to persuade the woman to choose childbirth over abortion." 112 S.Ct. at 2821. Second, "the State may enact regulations to further the health or safety of a woman seeking an abortion." Id. Neither of these interests, however, justify regulations which impose an undue burden on the right to seek a pre-viability abortion.

Because Casey only specifically mentioned these two interests, Plaintiff argues that any other interest--such as that of preventing unnecessary cruelty to the fetus during the abortion--is neither proper nor legitimate. Defendants argue that the interest is justified by the "State's profound interest in potential life throughout pregnancy," and that it would be contrary to logic and common sense to hold that this interest is not legitimate. The State further argues that if it is permitted to impose regulations which prevent cruelty to animals, then surely, it should be permitted to impose regulations which prevent cruelty to fetuses.

Again, this appears to be an issue of first impression before this, or any, Court. To this Court's knowledge, no abortion regulation has heretofore been justified by an interest in preventing unnecessary cruelty to the fetus. Moreover, this Court has no precedent to directly guide and inform its decision. There are, however, a few observations which help its analysis.

First, and foremost, this Court is mindful of Casey's strong recognition of the State's interest in potential life throughout the pregnancy. Second, although Casey only specifically delineated a few interests which the state has which justify regulation, nowhere in the opinion did the Court hold that no other state interest could justify regulations on pre-viability abortions. These observations, taken together, suggest that the state may impose regulations which vindicate its interest in the potential life of the fetus, based on interests other than those of persuading the woman to choose childbirth over abortion, or of protecting her health and safety. Finally, the Court agrees with Defendants that it would be contrary to all logic and common sense, to hold that a state has no interest in preventing unnecessary cruelty to fetuses.

Assuming arguendo that the interest is legitimate, however, Casey is clear in holding that regulations enacted to further legitimate interests may not impose an undue burden on the right to seek a pre-viability abortion. Because Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on D&X abortions would impose an undue burden on the right, the legitimacy of the state's interest, no matter how legitimate or compelling, will, in all likelihood, once the merits of this litigation are determined, not save the ban from being unconstitutional.

Although the Court need not, at this point, address the testimony concerning the cruelty of the D&X procedure--given that Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on the procedure is an undue burden and therefore is unconstitutional--it is in the public interest to discuss the issue of cruelty. Therefore, this Court now turns to the relevant testimony.

Defendants called two experts to testify to the pain felt by the fetus during the D&X procedure.[28]

Dr. Joseph Conomy is a professor of clinical neurology at Case Western Reserve University, and is involved in the issue of medical ethics. He has studied the formation of the nervous system, and has worked on problems of the nervous system in fetuses and newborn infants.

In regard to fetal neurology, Dr. Conomy testified that, at the age of twenty to twenty-four weeks, many of the neural pathways which transmit pain to the brain are established, although the cortical projections from the lower level of the brain, the thalamus, are not yet established (Tr., 11/13, at 301). It is his opinion, therefore, that pain can be transmitted to at least the lower levels of the brain at that age (Id. at 302).

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[28] Plaintiff Haskell testified that he didn't believe that fetal neurological development at twenty-four weeks would allow pain impulses to be transmitted to the brain (Tr., 11/8, at 179), and that a fetus of the same age lacked the cognitive ability to perceive pain (Id. at 180). Because Dr. Haskell was not qualified as an expert in the area of fetal neurology, this Court will not consider this testimony.

Dr. Conomy further testified that fetuses at the age of twenty to twenty-four weeks respond to nurturing stimuli, such as stroking the face, and noxious stimuli, such as pricking the skin, in different ways. Nurturing stimuli may cause a turning of the head, or pursing of the lips. Noxious stimuli will cause flexion and withdrawal (Id. at 300-302).

In reference to the D&X procedure, Dr. Conomy testified that it is his opinion that the procedure would prompt an unpleasurable stimulus to the fetus (Id. at 303). He also testified, however, that it would be "speculative" to try to "get inside the mind of a fetus, if there is one." (Id. at 301). Indeed, Dr. Conomy specifically refused to testify that a fetus can feel pain: although the fetus does "exhibit a class of responses that are characteristic of reflex response to obnoxious stimulation.... feeling is very much beyond that because it involves perception, designation, locality, and things that are far too speculative for me to assure you that a fetus feels." (Id. at 305). Thus, although Dr. Conomy testified that a fetus at the age of twenty to twenty-four weeks may physically respond to noxious stimuli, he did not testify that the fetus has a conscious, mindful awareness of the pain it is experiencing.

Finally, Dr. Conomy testified that a fetus who is aborted by the D&E procedure, which involves dismemberment, might experience as much discomfort as a fetus who is aborted by the D&X procedure (Id. at 307).

Defendants' second expert was Dr. Robert White, who is a professor of neurosurgery at Case Western Reserve University. He has been the director of a brain research laboratory for thirty years, but has not specifically studied pain or its mechanisms.

In his testimony, Dr. White defined "pain" as a physiological, or perhaps behavioral, expression resulting from the appreciation of a noxious stimulus (Tr., 12/7, at 119-120).

In particular reference to the mechanics of the D&X procedure, Dr. White testified that two maneuvers would cause pain to the fetus. First, the act of compressing, rotating, and pulling the fetus down into the birth canal--which also occurs during childbirth, at a more advanced age--must cause pain to the fetus (Id. at 131). Second, it was his opinion that the act of making an incision in the back of the neck and enlarging it--without, apparently, cutting any part of the nervous system--and then inserting a suction tube and evacuating the skull contents, must be painful (Id.).

Initially, Dr. White testified that it was his opinion that the fetus may feel pain during the D&X procedure; this answer was stricken from the record because it did not indicate an opinion within reasonable medical probability (Id. at 110-11). Later in his testimony, and after viewing a videotape of the procedure being performed on a dead fetus, Dr. White amended his opinion to state that the fetus can feel pain (Id. at 124). He based this opinion partly on the small size of the infant, which means that pain travels a much shorter distance than in adults, and partly on his opinion that chemicals in the brain which suppress pain are not established in fetuses, whereas, chemicals which reinforce pain are so established (Id. at 126-27). He also disputed Dr. Conomy's opinion that the cortical projections from the thalamus are not established at twenty-four weeks (Id. at 158-59).

In regard to whether a fetus at twenty-four weeks can consciously experience pain, Dr. White noted that the problem is "what we consider consciousness." (Id. at 162). He did admit, however, that he did not know "at what particular stage in the gestational [age] ... that an infant is conscious." (Id. at 163).

Finally, Dr. White testified that the D&E procedure would also be painful for the fetus, although the nervous system is more formed at twenty to twenty-four weeks, when the D&E procedure is used on a less frequent basis (Id. at 164).

Based on this testimony, this Court concludes the following: first, there is evidence that a fetus of age twenty to twenty-four weeks will react, physiologically, to noxious stimuli. Second, the evidence is inconclusive as to whether the pain impulses are transmitted to the higher levels of the brain at that age. Third, the evidence is inconclusive as to whether the D&X procedure is more painful than the D&E procedure.[29]

Finally, and most importantly, neither Dr. Conomy nor Dr. White testified that a fetus at age twenty to twenty-four weeks experiences a conscious awareness of pain. Although Defendants have suggested that there needn't be a conscious awareness of pain in order to conclude that the D&X procedure is "cruel," a finding that there is such a conscious awareness of pain on the part of the fetus does appear to be relevant to this Court; so, too, is the inability of the Court to make such a finding. Some might argue that abortion is always cruel because it ends in the death of the fetus; this, however, does not provide a basis for distinguishing between different methods of abortion. If the fetus does not perceive or experience the pain, then it is hard to see how the D&X procedure could be any more cruel than any other abortion method.

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[29] The parties stipulated that at the beginning of the D&X procedure, some fetuses are dead, and some are alive. An exact definition of the term "alive" was neither stipulated, nor clarified by the evidence. Indeed, in some basic, elemental sense, the fetus is "alive" from the moment of conception. What is clear, however, is that "alive" does not mean "viable." Were alive to mean viable, the stipulation arguably would be transformed into an acknowledgment that the D&X procedure is more cruel than either the D&E procedure, or any other form of mid-second trimester pregnancy terminations.

Assuming *arguendo* that the fetus does feel pain, one factor which suggests that the D&E procedure might be *more* painful than the D&X procedure--the physical act of dismembering the fetus in the D&E, as opposed to a relatively quick incision and suctioning process in the D&X--is balanced by the younger age of the fetus during the D&E procedure, which is performed earlier in the second trimester, when the nervous system is not as fully developed.

Assuming that the D&X procedure is "cruel," however, this Court fails to see how it is more cruel than the D&E procedure--which involves the dismemberment of the fetus and, sometimes, the crushing of its skull--or how it is always cruel, given that the fetus may already be dead (see Defendant's Exhibit R). The State's banning of the D&X procedure thus raises a question of whether its purpose in so doing was to prevent unnecessary cruelty, as stated, or, rather, was to place a significant obstacle in the path of a woman seeking a pre-viability abortion in the mid-second trimester. *Casey*, 112 S.Ct. at 2820. *Cf. Danforth*, 428 U.S. at 78 (discussing "the anomaly inherent in [the ban on saline amniocentisis] when it proscribes the use of saline but does not prohibit techniques that are many times more likely to result in maternal death").

This Court recognizes that the subject of when a fetus attains consciousness is a matter of great debate, and that reasonable minds can differ on the issue. As the Supreme Court stated in Casey:

> Men and women of good conscience can disagree, and we suppose some always shall disagree, about the profound moral and spiritual implications of terminating a pregnancy, even in its earliest stage. Some of us as individuals find abortion offensive to our most basic principles of morality, but that cannot control our decision. Our obligation is to define the liberty of all, not to mandate our own moral code.

112 S.Ct. at 2806. Until medical science advances to a point at which the determination of when a fetus becomes "conscious" can be made within a reasonable degree of certainty, neither doctors nor judges nor legislators can definitively state when an abortion procedure becomes "cruel," in the sense of when the fetus becomes aware of pain. That judgment must be made by each individual member of society.

Given that there is no reliable evidence that the D&X procedure is more cruel than other methods of abortion, this Court is unable to conclude that the ban on the use of the D&X procedure serves the stated interest of preventing unnecessary cruelty to the fetus.[30] As in *Danforth*, the ban on the D&X procedure therefore "comes into focus, instead, as an unreasonable or arbitrary regulation designed to inhibit, and having the effect of inhibiting," second-trimester abortions prior to viability. 428 U.S. at 79.

This conclusion does not, however, mean that the state cannot regulate the D&X procedure, short of an absolute ban. As discussed above, Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on the D&X procedure is unconstitutional, because it imposes an undue burden on the right to seek a pre-viability abortion, and because the definition of D&X is vague. Assuming, however, that the fetus is conscious of the pain involved in the D&X procedure, it appears to this Court that the state could still seek to vindicate its asserted interest in preventing arguably unnecessary cruelty to the fetus, by regulating the procedure without banning it outright.

Although the testimony on this issue was not conclusive, one such possible regulation may require the physician to cut the umbilical cord prior to making an incision in the base of the skull, and to wait until the fetus dies as a result. Another possible regulation might require the use of local or general anesthetic, on the fetus or the mother. By use of such regulations, states could prevent arguably unnecessary cruelty in the abortion procedure, without taking away the right to seek a pre-viability abortion. In enacting any regulation on the D&X procedure, however, states must bear in mind that they cannot reduce either the safety or the availability of the procedure. Such an effect would render the regulation unconstitutional under both Danforth and Casey.

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[30] Before *Casey*, the State would have had to show that the ban on the D&X procedure was necessary to achieve a compelling state interest, under a strict scrutiny standard. After *Casey*, the State need only show that it has a legitimate interest, and that the challenged regulation "cannot be said [to] serve no purpose other than to make abortions more difficult." 112 S.Ct. at 2833. This new approach appears to require courts to examine whether the challenged regulation serves the stated, legitimate purpose. *See*, *e.g.*, *Barnes v. Mississippi*, 992 F.2d 1335, 1340 (5th Cir.) (holding that because the challenged two-parent consent statute helped to safeguard the interests of both parents and the family, it could not be said to serve no purpose other than to make abortions more difficult), *cert. denied*, 114 S.Ct. 468 (1993). Accordingly, this Court must examine whether the ban on the D&X procedure serves the purpose of preventing unnecessary cruelty to the fetus.

D. The Ban on Post-Viability Abortions

1. Description of the Statute

Because the challenged ban on post-viability abortions is particularly complex, it is advisable to provide a detailed overview of all of the provisions before proceeding to analyze them individually.

House Bill 135 bans the performance of all post-viability abortions, unless:

> (1) the physician determines, in good faith and in the exercise of reasonable medical judgment, that the abortion is necessary to prevent the death of the pregnant woman or [medically necessary to prevent] a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman, [or]
>
> (2) the physician determines, in good faith and in the exercise of reasonable medical judgment, after making a determination relative to the viability of the unborn human in conformity with [§ 2919.18(A)], that the unborn human is not viable.

O.R.C. § 2919.17(A)(1-2). The statute defines a serious risk of the substantial and irreversible impairment of a major bodily function as follows:

> [A]ny medically diagnosed condition that so complicates the pregnancy of the woman as to directly or indirectly cause the substantial and irreversible impairment of a major bodily function, including, but not limited to, the following conditions: (1) pre-eclampsia; (2) inevitable abortion; (3) prematurely ruptured membrane; (4) diabetes; (5) multiple sclerosis.

O.R.C. § 2919.16(J). This definition appears to limit the legality of post-viability abortions to situations where an abortion is required to preserve the woman's physical health, as opposed to her emotional or psychological health.

If the first exception applies (the abortion is medically necessary), the physician must conform with a number of requirements governing the performance of the abortion, unless a medical emergency exists. The statute sets forth five specific conditions which must be satisfied:

> (a) the physician who performs ... the abortion certifies in writing that that physician has determined, in good faith and in the exercise of reasonable medical judgment, that the abortion is necessary to prevent the death of the pregnant woman or a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman.
>
> (b) the determination of [that] physician ... is concurred in by at least one other physician who certifies in writing that the concurring physician has determined, in good faith, in the exercise of reasonable medical judgment, and following a review of the available medical records of and any available tests pertaining to the pregnant woman, that the abortion is necessary to prevent the death of the pregnant woman or a serious risk of the

> substantial and irreversible impairment of a major bodily function of the pregnant woman.
>
> (c) the abortion is performed ... in a health care facility that has or has access to appropriate neonatal services for premature infants.
>
> (d) the physician ... terminate[s] the pregnancy in the manner that provides the best opportunity for the unborn human to survive, unless that physician determines, in good faith and in the exercise of reasonable medical judgment, that the termination of the pregnancy in that manner poses a significantly greater risk of the death of the pregnant woman or a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman than would other available methods of abortion.
>
> (e) the physician ... has arranged for the attendance in the same room in which the abortion is to be performed ... of at least one other physician who is to take control of, provide immediate medical care for, and take all reasonable steps necessary to preserve the life and health of the unborn human immediately upon the unborn human's complete expulsion or extraction from the pregnant woman.

O.R.C. § 2919.17(B)(1)(a-e). These requirements may be summarized as follows: (1) the certification requirement, (2) the second physician concurrence requirement, (3) the neonatal facility requirement, (4) the choice of method requirement, and (5) the second physician attendance requirement.

In the event of a medical emergency, some or all of these requirements may be waived. The statute defines a medical emergency as:

> [A] condition that a pregnant woman's physician determines, in good faith and in the exercise of reasonable medical judgment, so complicates the woman's pregnancy as to necessitate the immediate performance or inducement of an abortion in order to prevent the death of the woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman

> that delay in the performance or inducement of the abortion would create.

O.R.C. § 2919.16(F). If a medical emergency exists, and is such that the physician cannot comply with one or more of the conditions, the physician may perform the abortion without fulfilling those statutory requirements.

The statute also creates a rebuttable presumption of viability at twenty-four weeks of gestational age. O.R.C. § 2919.17(C). The statute defines gestational age as:

> [T]he age of an unborn human as calculated from the first day of the last menstrual period of a pregnant woman.

O.R.C. § 2919.16(B).

A person who violates any of the above provisions is guilty of the crime of terminating a human pregnancy after viability, a fourth-degree felony. O.R.C. § 2919.17(D). In addition, that person may be civilly liable for compensatory and punitive damages. O.R.C. § 2307.52(B).

Plaintiffs have challenged seven separate provisions of this ban: (1) the determination of non-viability, (2) the definition of serious risk of the substantial and irreversible impairment of a major bodily function, (3) the definition of medical emergency, (4) the second physician concurrence requirement, (5) the choice of method requirement, (6) the second physician attendance requirement, and (7) the presumption of viability, including the statutory definition of gestational age. This Court will consider each of these challenges separately.

2. Determination of Non-viability

As noted, one exception to the ban on post-viability abortions allows a performance of a late-term abortion if the fetus is determined not to be viable. House Bill 135 defines viable as:

> [T]he stage of development of a human fetus at which in the determination of a physician, based on the particular facts of a woman's pregnancy that are known to the physician and in light of medical technology and information reasonably available to the physician, there is a realistic possibility of the maintaining and nourishing of a life outside of the womb with or without temporary artificial life-sustaining support.

O.R.C. § 2919.16(L) (emphasis added). This definition appears to allow the physician to rely on his own best clinical judgment in determining whether a fetus is viable.

The statute directs, however, that the physician cannot perform a late-term abortion unless the fetus is non-viable, as determined in the following manner:

> [T]he physician determines, in good faith and in the exercise of reasonable medical judgment, that the unborn human is not viable, and the physician makes that determination after performing a medical examination of the pregnant woman and after performing or causing the performing of gestational age, weight, lung maturity, or other tests of the unborn human that a reasonable physician making a determination as to whether an unborn human is or is not viable would perform or cause to be performed.

O.R.C. § 2919.18(A)(1) (emphasis added). Under this provision, it appears that the physician cannot rely solely on his or her own best clinical judgment in determining whether a fetus is viable; instead, that determination must be objectively reasonable as well, that is, reasonable to other physicians, as well as to the physician making the determination.[31]

Plaintiff argues that because one provision (the definition of "viable") suggests that a viability determination may be made based on a physician's own best clinical judgment, whereas another provision (the determination of non-viability) requires that determination to be reasonable to other physicians as well, the statute is unclear as to what standard will be applied, and, thus, is unconstitutionally vague. This Court agrees that the quoted provisions of the statute set forth different standards for judging the legality of the physician's determination, and, thus, that Plaintiff has demonstrated a substantial likelihood of success of showing that the determination of non-viability, as required to satisfy one exception to the post-viability ban, at O.R.C. § 2919.17(A)(2), is unconstitutionally vague, because it fails to provide the physician with fair warning of what legal standard will be applied, and, therefore, of what conduct will incur criminal and civil liability.[32]

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[31] The Court draws this conclusion for two reasons. First, if the term "in the exercise of reasonable medical judgment" were a subjective standard, referring to the physician's own judgment, there would be no need to also require the physician to act "in good faith." It is a maxim of statutory construction that no word or words should be construed in such a way that they are surplusage.

Second, the term "reasonable," as it is used in the law generally, almost always incorporates an objective standard. The term "reasonable belief," for example, is commonly used to indicate both that the actor himself holds a belief, and that a reasonable man would hold that belief under the same circumstances. Black's Law Dictionary 874 (6th ed. 1991). The term "reasonable care" means "that degree of care which a person of ordinary prudence would exercise in the same or similar circumstances." Id. at 875. The term "reasonable cause" refers to the "basis for arrest without warrant, [with] such state of facts as would lead a man of ordinary care and prudence to believe ... that the person sought to be arrested is guilty of committing a crime." Id. These examples, which are not exhaustive, demonstrate that the term "reasonable" generally indicates a requirement that the action be reasonable to others. Absent a clear statutory intent to the contrary, this Court must construe the term "in the exercise of reasonable medical judgment" as incorporating an objective standard.

3. Definition of "Serious Risk of Substantial and Irreversible Impairment of a Major Bodily Function"

The other exception to the post-viability ban requires a determination that the abortion is necessary to avert the death of the pregnant woman, or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function. The statute defines the term "serious risk of the substantial and irreversible impairment of a major bodily function" as follows:

> [A]ny medically diagnosed condition that so complicates the pregnancy of the woman as to directly or indirectly cause the substantial and irreversible impairment of a major bodily function, including, but not limited to, the following conditions: (1) pre-eclampsia; (2) inevitable abortion; (3) prematurely ruptured membrane; (4) diabetes; (5) multiple sclerosis.

O.R.C. § 2919.16(J). This definition appears to limit the legality of post-viability abortions to situations where an abortion is required to preserve the woman's physical health.

Plaintiff argues that this definition is too narrow, and does not allow the physician to consider other factors which relate to the woman's health, including psychological and emotional factors. Plaintiff cites to a Supreme Court abortion case decided before abortion was legalized in Roe v. Wade, which discussed a statute that outlawed abortions except where a doctor determined that the abortion was necessary to preserve the mother's life or health:

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[32] Standing alone, the statute's definition of viable would appear to be unobjectionable, because it contains a purely subjective standard. In contrast, it could be argued that the determination of viability is void, either because its lack of a scienter requirement creates vagueness, or because the objective reasonableness standard will chill the physician's determination of non-viability, and create an undue burden. For this reason, this Court holds that the determination of non-viability, but not the definition of viable, is unconstitutional.

> We agree ... that the medical judgment may be exercised in the light of all factors--physical, emotional, psychological, familial, and the woman's age--relevant to the well-being of the patient. All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment. And it is room that operates for the benefit, not the disadvantage, of the pregnant woman.

Doe v. Bolton, 410 U.S. 179, 192 (1973). Plaintiff argues that House Bill 135 impermissibly limits the physician's discretion to determine whether an abortion is necessary to preserve the woman's health, because it limits the physician's consideration to medical factors relating to physical health.[33]

Defendant, however, cites to the Supreme Court's more recent decision in Casey, which upheld a similar definition of serious risk of the substantial and irreversible impairment of a major bodily function, that also limited the physician's determination to consideration of medical factors. 112 S.Ct. at 2822. Defendant argues that the Supreme Court's decision in Casey governs here.

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[33] The testimony in this case indicates that physicians do routinely consider non-medical factors that relate to health, when counseling women about having an abortion. Dr. Paula Hillard testified that she "takes into account the circumstances of the pregnancy which may be a result of rape or incest. So, I take into account the psychological health of the individual." (Tr., 11/8, at 29). Dr. John Doe Number Two testified that he deals with his patients "in a holistic approach, encompassing not only the physical consequences of the patient's particular situation, but encompassing her psychological well-being, both short and long term." (Tr., 12/7, at 22).

Plaintiff responds by pointing out that the challenged definition in Casey did not have the effect of preventing the performance of an abortion, altogether; instead, it merely allowed for an exception to the informed consent requirement, the 24-hour waiting period, and the parental consent provision. Thus, Plaintiff argues, the application of this definition to the challenged ban on post-viability abortions will have a more severe impact than it did in Casey, because it will completely prevent, and not merely delay, abortions that may be necessary to preserve the mother's overall health.

The testimony of Jane Doe Number Two is illustrative of how severe this impact may be. This witness testified to the pain and suffering she and her husband experienced when they discovered, during her twenty-second week of pregnancy, that their baby lacked a spine, had malfunctioning kidneys, and a clubbed foot (Tr., 12/6, at 151-53). A neonatal specialist advised them that after the baby was born, it would be paralyzed, at least from the waist down, would require immediate kidney dialysis, would need major surgery within thirty minutes of birth, and would probably be hydrocephalic (have water on the brain) (Id. at 154). Before this discovery, the witness testified that all indications pointed to an uneventful pregnancy (Id. at 155).

Jane Doe Number Two and her husband decided to terminate the pregnancy, rather than carry the baby to term. She explained their decision as follows:

> Just finding out about this, mentally, it just -- it crushed both of us. We were excited. We wanted a baby very badly. We had prayed for a girl, and I guess there was guilt involved because maybe we didn't pray for [the baby to be] healthy. And you felt selfish.
>
> I kept thinking, What did I do? You know, I didn't smoke. I didn't drink. I was eating right. This has to be one of our fault's. It has to be somebody's fault in some way that we're going through this....
>
> I couldn't imagine mentally going to term. When I found this out, it was on a Friday, and I had my [abortion] procedure scheduled for Tuesday; and just, during that time, all we did was cry, we beat ourselves up about what could we have done differently, when there was nothing we could have done.
>
> I just -- if I had to carry that baby to term, I am not sure I would have chosen to have children again.

Id. at 155-56. Jane Doe Number Two terminated her pregnancy by use of the D&X procedure, which was performed by Dr. Haskell. She testified that it was important to her that the fetus be intact, in order have an autopsy performed, and thereby to determine whether a genetic defect had caused the fetal anomalies (Id. at 158). The autopsy results indicated that the defect was not genetic. She and her husband have since had twin girls.

Under House Bill 135, it seems probable that a physician would have been forced to determine that Jane Doe Number Two's fetus had a realistic possibility of living after birth with life-sustaining support, although its prognosis was dismal. Therefore, if this Act had been in effect, Jane Doe Number Two would have been forced to carry her baby to term, because there was no threat to her physical health, even though it seems clear that this would have been very damaging to her mental and emotional health.

It is also possible that a pregnant woman who is faced with such a law, and who is carrying a fetus with severe anomalies, might feel forced to abort her pregnancy before her twenty-fourth week of pregnancy merely in order to avoid the ban, even if she would prefer to try some measure, such as fetal surgery, to mitigate or cure the anomaly.

This possibility is suggested by the testimony of another of Dr. Haskell's patients, Jane Doe Number One, who terminated her most recent pregnancy on November 30, 1995. She first learned that there was a problem in her sixteenth week of pregnancy, when it was discovered that her baby had a bladder obstruction and could not urinate (Tr., 12/5, at 16-17). Once it was determined that the kidneys were functioning and that the baby was making good urine, this witness traveled to Detroit and underwent surgery to alleviate the bladder obstruction, in her eighteenth week (Id. at 17-18). That surgery was successful; however, the baby's ureter did not function properly, and the baby's right kidney failed as a consequence (Id.).

In her twentieth week of pregnancy, Jane Doe Number One traveled back to Detroit, and learned that her baby suffered from "prune belly syndrome." (Id. at 19). After reading about the syndrome and consulting with their physician, the witness and her husband learned that their baby only had a twenty percent chance of survival at birth, that he would need a kidney transplant, and that he would probably die before the age of two (Id. at 19-20).

Jane Doe Number One was now in her twenty-second week of pregnancy. She and her husband consulted with their own doctor and a pediatric urologist, and then decided to terminate the pregnancy. She explained why they decided to have an abortion:

> Because the prognosis was so poor. We had seen that the left kidney had already become involved, and the left ureter was dilated. So, we felt certain that that kidney was going to fail, and we felt that the baby was not going to survive.... It's terribly agonizing to have a baby growing inside of you and to feel him kick and to know that he won't live. It's terrible.

Id. at 21. During her twenty-fourth week of pregnancy, Jane Doe Number One received an abortion by use of the D&X procedure, which was performed by Dr. Haskell. She compared her experience with the D&X procedure to a previous abortion by use of an induction procedure, by which she terminated another pregnancy with severe fetal anomalies:

> Physically ... there is no comparison. There was minimal pain. I was alert the entire time, and the procedure took, I would say, about an hour to an hour and a half. Physically, the [D&X] procedure is much -- it's terrible to say it was easier or better, but the procedure was much easier to endure.

Id. at 22-23. She testified that it was definitely helpful to have the D&X procedure available to her (Id. at 24).

In addition, Jane Doe Number One expressed concern that House Bill 135 would have forced her to make a decision to terminate the baby before she had the opportunity to do everything possible to save it:

> In our situation, the kidneys were involved, and ... the baby's kidneys don't function until week sixteen or eighteen. So, therefore, we would not have known, or couldn't know, that there was a problem and totally tried to help the baby and make him a viable baby prior to that time. We'd have lost the opportunity .... We wouldn't have had a choice, or as many choices.

Id. Because her physical health would not have been threatened by carrying the baby to term, Jane Doe Number One would not, under House Bill 135, have been permitted to terminate her pregnancy after her baby was deemed to be viable.

The testimony of these two witnesses demonstrates the problems with House Bill 135's narrow definition of "serious risk of the substantial and irreversible impairment of a major bodily function," and its limitation to strictly medical factors. First, as in the case of Jane Doe Number Two, this definition will force women to carry babies to term which are likely to die before birth or immediately thereafter, or which have a prognosis so poor that its parents feel it would be best to terminate the pregnancy. This result could have a severe, negative impact on the mental and emotional health of the pregnant woman, as well as on the mental and emotional health of the baby's father. Second, as in the case of Jane Doe Number One, the possibility of being required to carry a severely deformed fetus to term might prompt pregnant women who are carrying fetuses with severe anomalies to abort before their twenty-fourth week, simply in order to avoid the ban, even if they would prefer first to attempt some measures to improve their baby's chances of survival.

Finally, although there was no direct testimony from a victim of rape or incest, Dr. Hillard did testify about an eleven-year-old victim of incest, whose pregnancy was not diagnosed until approximately her twenty-second week, at which time legal charges were brought against her father (Tr., 11/8, at 52). The girl and her mother then requested that the pregnancy be terminated, and Dr. Hillard performed the procedure. Under House Bill 135, Dr. Hillard would have had to perform viability testing before terminating the pregnancy; if the fetus had been adjudged to be viable, and there were no physical threat to the girl's health, she would have been forced to carry her pregnancy to term. In this Court's view, it is inconceivable that the act of being forced to bear her father's child, could have failed to have a severe, negative, and lasting impact on this girl's emotional and psychological health.

The issue of whether a state may ban post-viability abortions except where necessary to preserve the woman's physical health, even if carrying the baby to term would cause her to suffer severe mental or emotional harm, appears to be an issue of first impression before this, or any, Court.

Under the authority of Doe v. Bolton, discussed above, this Court holds that a state may not constitutionally limit the provision of abortions only to those situations in which a pregnant woman's physical health is threatened, because this impermissibly limits the physician's discretion to determine what measures are necessary to preserve her health.[34] Casey is not dispositive of this issue, because it only considered restrictions which delayed, but did not prevent, pre-viability abortions; whereas, in this case, the statute will completely prevent the performance of post-viability abortions that may, in appropriate medical judgment, be necessary to preserve the health of the pregnant woman. Under Casey, such a regulation is clearly unconstitutional. 112 S.Ct. at 2821. Accordingly, Plaintiff has demonstrated a substantial likelihood of success of showing that the Act's definition of "serious risk of the substantial and irreversible impairment of a major bodily function," which is limited to strictly medical factors in application to the ban on post-viability abortions, is unconstitutional.[35]

4. Definition of "Medical Emergency"

In its explanation of its Temporary Restraining Order, granted on November 13, 1995, this Court stated that Plaintiff had demonstrated a substantial likelihood of success of showing that the medical emergency definition was unconstitutional on two grounds: first, it lacked a mens rea, or scienter, requirement, and therefore was vague; second, it did not allow physicians to rely solely on their own best clinical judgment in determining that a medical emergency existed, and so would chill physicians from exercising their best medical judgment in deciding whether such an emergency exists.[36] Most of that discussion will be repeated here. In addition, the Court will address the effect of O.R.C. § 2901.21, which could potentially allow this Court to import a scienter requirement of "recklessness" into the medical emergency definition.

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[34] In addition, as highlighted by Jane Doe Number One's testimony, an exception which is limited only to preserving the pregnant woman's physical health may run the risk of impermissibly limiting the physician's discretion—and the mother's decision—to take whatever steps may be helpful (surgical or otherwise) in dealing with the specific problems facing that unborn child.

[35] As discussed in an earlier part of the opinion, this Court concludes that it need not apply the Salerno standard to restrictions on post-viability abortions, and that a pregnant woman may therefore succeed in a facial challenge to such a regulation, even if she cannot show that "no set of circumstances exists under which the law would be valid."

Before turning to the Act itself, it is advisable to define the meaning of the terms "scienter" and "mens rea", and to describe their importance in the law. The term "scienter" means "knowingly" and is "frequently used to signify the defendant's guilty knowledge." Black's Law Dictionary 1207 (5th ed. 1979). The term "mens rea" refers to a "guilty mind, a guilty or wrongful purpose, a criminal intent." Id. at 889. Both of these terms require that a defendant have some degree of guilty knowledge, or some degree of blameworthiness or culpability, in order to be criminally liable. Statutes which do not contain such a requirement, and which impose criminal liability even if the defendant did not knowingly violate the law, or did not have a culpable state of mind, are known as "strict liability" statutes.

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[36] On this point, it is significant that, as far as this Court is aware, no other court has been confronted with a medical emergency definition that includes an objective requirement, and therefore does not permit the physician to rely solely on his or her best clinical judgment.

This objective requirement seems certain to create a chilling effect--particularly given the lack of a scienter requirement. Even if the statute had a scienter requirement, it might still have a chilling effect, though to a lesser extent, given that the physician would still be subject to prosecution if other physicians disagreed with his or her determination. This Court therefore takes no position on whether an objective requirement in a medical emergency definition, with or without a scienter requirement, is also void for vagueness.

There is a strong presumption in our law favoring a mens rea or scienter requirement in statutes which create criminal liability. See Staples v. United States, 114 S.Ct. 1793, 1797 (1994) ("we must construe the statute in light of the background rules of common law ... in which the requirement of some mens rea for a crime is firmly embedded"); United States v. United States Gypsum Co., 438 U.S. 422, 437-38 (1978) ("the limited circumstances in which Congress has created and this Court has recognized [strict-liability] offenses... attest to their generally disfavored status"); Dennis v. United States, 341 U.S. 494, 500 (1951) ("the existence of a mens rea is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence"). The rationale for this presumption was eloquently set forth by Justice Jackson:

> The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil. A relation between some mental element and punishment for a harmful act is almost as instinctive as the child's familiar exculpatory "But I didn't mean to"....
>
> The unanimity with which [courts] have adhered to the central thought that wrongdoing must be conscious to be criminal is emphasized by the variety, disparity and confusion of their definitions of the requisite but elusive mental element... [including] such terms as "felonious

> intent," "criminal intent," "malice aforethought," "guilty knowledge," "fraudulent intent," "willfulness," "scienter," to denote guilty knowledge, or "mens rea," to signify an evil purpose or mental culpability. By use or combination of these various tokens, they have sought to protect those who were not blameworthy in mind from conviction of infamous common-law crimes.

Morissette v. United States, 342 U.S. 246, 250-52 (1952) (emphasis added). Although the presumption favoring a mens rea requirement is not as strong in statutes creating civil liability, because House Bill 135 imposes civil and criminal liability for the same actions, this Court must analyze the provisions of the Act in light of the presumption of a mens rea requirement. Having described the meaning and importance of a "guilty knowledge" requirement in laws creating criminal liability, this Court now turns to House Bill 135.

The medical emergency exception, which is defined in Ohio Revised Code section 2919.16(F), is employed in the ban on post-viability abortions. This Court concludes that because, under the definition of medical emergency, a physician may not rely alone on his own good-faith clinical judgment in determining that a medical emergency exists, and because both the medical emergency definition and provisions imposing criminal liability for violations of section 2919.17 lack scienter requirements, Plaintiff has demonstrated a substantial likelihood of success of showing that the medical emergency definition in the Act is unconstitutional.

House Bill 135 defines a medical emergency as follows:

> "Medical emergency" means a condition that a pregnant woman's physician determines, in good faith and in the exercise of reasonable medical judgment,

> so complicates the woman's pregnancy as to necessitate the immediate performance or inducement of an abortion in order to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman that delay in the performance or inducement of the abortion would create.

O.R.C. § 2919.16(F) (emphasis added). This definition includes subjective and objective requirements: the physician must believe, himself, that the abortion is necessary, and his belief must be objectively reasonable to other physicians. Under this definition, a finding that the physician failed to act in good faith is therefore not necessary to impose civil and criminal liability. One could act in good faith and according to one's own best medical judgment, and yet incur civil and criminal liability if, after the fact, the exercise of that medical judgment is determined by others to have been not objectively reasonable. In other words, physicians need not act willfully or recklessly in determining that a medical emergency exists in order to incur criminal liability; instead, they face liability even if they act in good faith, and according to their own best (albeit, in the later opinion of others, mistaken) medical judgment. Thus, this definition appears to create strict liability, that is, liability even if the physician acts in good faith, and without a culpable mental state, to comply with the statute.

Although this Court is unaware of any case which has considered the constitutionality of a similar provision, there are three cases which this Court finds to be relevant. In

Colautti v. Franklin, 439 U.S. 379, 396 (1979), the Supreme Court held unconstitutional a Pennsylvania provision which required physicians to determine non-viability before performing an abortion. If a physician failed to abide by specific requirements where there was "sufficient reason" to believe that the fetus "may be viable," he was civilly and criminally liable. Id. at 394. No language in the statute indicated that liability was to be predicated on a culpable state of mind. Id. at 380, n.1. The determination of non-viability was to be based on the physician's "experience, judgment, or professional competence." Id. at 380 n.1.

In concluding that the provision did not contain a scienter requirement, the Court found that neither Pennsylvania criminal law nor the Act itself "requires that the physician be culpable in failing to find sufficient reason to believe that the fetus may be viable." Id. at 394-95. The Court also noted that the subjective standard in the Act which is "keyed to the physician's individual skills and abilities ... is different from a requirement that the physician be culpable or blameworthy for his performance...." Id. at 395 n.12. The Supreme Court then held the provision void for vagueness due to its lack of a mens rea requirement:

> This Court has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of mens rea. Because of the absence of a scienter requirement in the provision directing the physician to determine whether the fetus is or may be viable, the statute is little more than a 'trap for those who act in good faith.'

> The perils of strict criminal liability are particularly acute here because of the uncertainty of the viability determination itself. As the record in this case indicates, a physician determines whether or not a fetus is viable after considering a number of variables .... In the face of these uncertainties, it is not unlikely that experts will disagree .... The prospect of such disagreement, in conjunction with a statute imposing strict civil and criminal liability for an erroneous determination of viability, could have a profound chilling effect on the willingness of physicians to perform abortions ... in the manner indicated by their best medical judgment.

Id. at 395-96 (citations omitted) (emphasis added).

Colautti is directly applicable to this case, insofar as the determination of whether a medical emergency exists is similarly fraught with uncertainty, and is therefore equally susceptible to being disputed by experts at a later date, thereby resulting in criminal liability even where the physician acted in good faith. As noted, the medical emergency exception in House Bill 135 contains both a subjective and an objective requirement. Because both of these requirements must be met in order for the physician to avoid liability, and because there is no scienter requirement in this provision, a physician who performs a post-viability abortion under the medical emergency exception may be held liable even if he or she acted in good faith, as long as the physician was later determined, in the eyes of others, using 20/20 hindsight, to have acted unreasonably. Plaintiffs have demonstrated a substantial likelihood of success of showing that, given the short amount of time in which every decision regarding a medical emergency must be made, and given the varying, highly individual factors which must be considered for each case, it is not unlikely that even where a physician acts in good faith, experts may later disagree as to the existence, immediacy, or extent of a medical emergency. As in Colautti, this prospect of disagreement, combined with the strict civil and criminal liability for even good-faith determinations, could chill physicians from performing post-viability abortions even where it is their best medical judgment that an abortion is required to preserve the life or health of a patient.

In so finding, this Court acknowledges that the "undue burden" analysis in Planned Parenthood v. Casey, 112 S.Ct. 2791 (1992), applies only to pre-viability abortions, and therefore does not apply to this provision governing the performance of post-viability abortions. Although it may seem that this would render any "chilling effect" irrelevant, this is manifestly not the case. In Casey, the Supreme Court recognized that the State's interest in the life of the fetus allows it to regulate or proscribe abortions after viability, except "where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." 112 S.Ct. at 2821. Such is the situation here. If physicians were chilled from acting according to their own best medical judgment when determining whether a post-viability abortion is necessary to save the life of the mother, and were forced to resolve even the smallest doubt in favor of a refusal to act, this could have a profound, negative impact on the State's interest in preserving the life and health of the mother, and on the pregnant woman's interest in her own life and health. It is this Court's belief that such a situation would offend the Constitution to an even greater degree than those situations in which a chilling effect precludes the performance of elective pre-viability abortions, which are not necessary to preserve the mother's life or health. Therefore, the analysis in Colautti is applicable to this case.

A more recent case which addresses this issue is Planned Parenthood, Sioux Falls Clinic v. Miller, 63 F.3d 1452 (8th Cir. 1995). In that case, the Court invalidated provisions regarding the performance of abortions which created civil and criminal liability for violations of South Dakota's parental-notice, mandatory-information, and medical-emergency requirements. The medical emergency provision in that case did not require the physician either to act in good faith, or to apply reasonable medical judgment; instead, it merely provided:

> If a medical emergency compels the performance of an abortion, the physician shall inform the female, prior to the abortion if possible, of the medical indications supporting his judgment that an abortion is necessary to avert her death or that delay will create serious risk of substantial and irreversible impairment of a major bodily function.

Id. at 1455 n.4. Other provisions imposed civil and criminal liability for violation of the medical emergency provision:

> [§ 34-23A-22] If an abortion occurs which is not in compliance with [the medical emergency provision], the person upon whom such an abortion has been

> performed ... may maintain an action against the person who performed the abortion for ten thousand dollars in punitive damages and treble whatever actual damages the plaintiff may have sustained.
>
> [34-23A-10.2] A physician who violates [the medical emergency provision] is guilty of a Class 2 misdemeanor.

Id. at 1455-56 n.5-6. None of these provisions contained a scienter or mens rea requirement on their face.

The District Court found that the provision creating criminal liability lacked a mens rea requirement, which "made it unconstitutionally vague, creating a 'chilling effect' so that physicians, who cannot guess the standard under which the courts will judge their conduct, would choose not to act at all." Id. at 1463. The District Court also invalidated the civil liability provision on similar grounds, after concluding that strict civil liability created an undue burden because it made it unlikely that any physician would perform abortions. Id.

The Eighth Circuit affirmed the lower court's decision, due to the statute's lack of a scienter requirement. It agreed that the provision creating criminal liability would create an undue burden by chilling the willingness of physicians to perform abortions. Id. at 1465. It further agreed that the provision creating civil liability--which did not require a finding that the defendant acted willfully, wantonly, or maliciously, before awarding punitive damages--was invalid:

> The potential civil liability for even good-faith, reasonable mistakes is more than enough to chill the willingness of physicians to perform abortions in

> South Dakota. We therefore hold that [this provision] is an undue burden on a woman's right to choose whether to terminate her pre-viability pregnancy.

Id. at 1467.

As noted, the medical emergency exception in House Bill 135 could impose civil and criminal liability even where the physician acted in good faith. Plaintiffs have demonstrated a substantial likelihood of success of showing that, given the fact that reasonable physicians might disagree as to the existence or immediacy of a medical emergency, this provision would create liability even for good-faith, reasonable mistakes. As in Miller, this result would chill the willingness of physicians to perform post-viability abortions even where they are necessary, in a medical emergency, to preserve the life and health of the mother.

A third case which supports this Court's findings is the Eighth Circuit's decision to uphold the North Dakota definition of a medical emergency, because it allowed the physician to rely on his or her own "best clinical judgment" in determining whether an emergency existed, and because the statute contained a scienter requirement. Fargo Women's Health Org. v. Schafer, 18 F.3d 526, 534 (8th Cir. 1994) ("It is the exercise of clinical judgment that saves the statute from vagueness... In addition, the North Dakota Act contains a scienter requirement that we believe prevents a finding of vagueness."). Accord Barnes v. Moore, 970 F.2d 12, 15 (5th Cir. 1992) (upholding medical emergency definition which allowed physician to rely on "best clinical judgment" and contained scienter requirement for imposition of criminal liability). The statute at issue in Schafer defined a "medical emergency" as:

> that condition which, on the basis of the physician's best clinical judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the death of the mother or for which a twenty-four hour delay will create grave peril of immediate and irreversible loss of major bodily function.

Id. at 527, n.3 (emphasis added). Although the North Dakota statute did not expressly contain a scienter requirement, North Dakota criminal statutes which neither specify culpability, nor explicitly provide that culpability is not required, are construed as requiring a "willful" violation of the statute, which is further defined as conduct done "intentionally, knowingly, or recklessly." Id. at 534-35. Thus, although the statute containing the medical emergency definition was silent on the question of intent, the Eighth Circuit imported a scienter requirement into the statute.

The medical emergency definition in House Bill 135 differs in two significant respects from the definition in Schafer. First, the definition in House Bill 135 does not allow the physician to rely solely on his or her own best, good-faith medical judgment; instead, in addition to requiring that he or she act in good faith, it requires the physician to apply "reasonable medical judgment," which is an objective requirement, subject to second-guessing by other physicians. Second, the medical emergency provision creates strict liability because it lacks a scienter requirement; in addition, the provisions creating criminal liability for violations of the ban on post-viability abortions, and of the viability testing requirement--both of which apply the medical emergency exception--lack scienter requirements. Therefore, the medical emergency exception in House Bill 135 appears to fail both of the tests upon which the North Dakota definition was held to be valid.

In its earlier opinion which explained its Temporary Restraining Order, this Court incorrectly stated that Ohio law does not allow courts to import a scienter requirement into criminal statutes that are silent on the issue of whether intent is a required element, relying on State v. Curry, 43 Ohio St.2d 66; 330 N.E.2d 720 (Ohio 1975) ("If the statute is silent on the question of intent, intent is not an element of the crime."). Plaintiff correctly pointed out that an Ohio law enacted immediately prior to Curry (although inapplicable to the facts in Curry, which arose prior to the effective date of the statute) might, however, allow this Court to import a scienter requirement into the medical emergency definition, even though that definition does not include any intent requirement. Section 2901.21(B) of the Ohio Revised Code provides that:

> When the section defining an offense does not specify any degree of culpability, and plainly indicates a purpose to impose strict criminal liability for the conduct described in such section, then culpability is not required for a person to be guilty of the offense. When the section neither specifies culpability nor plainly indicates a purpose to impose strict liability, recklessness is sufficient culpability to commit the offense.

Thus, if the statute does not plainly indicate an intent to impose strict liability, Ohio courts could import a scienter requirement of recklessness into the statute.

For two reasons, it is this Court's opinion that Ohio courts would decline to import a recklessness standard into the statute's requirement that a physician act "in the exercise of reasonable medical judgment" when determining whether a medical emergency exists.

First, both sections of the statute which apply the medical emergency definition--the ban on post-viability abortions, and the viability testing requirement, discussed infra--plainly indicate an intention to impose strict liability. Both of these sections state that "no person shall" perform the proscribed acts, and fail to specify any mental state. Ohio courts have held that similar laws which lack culpable mental states, and contain the term "no person shall...," plainly indicate an intention to impose strict liability. State v. Cheraso, 43 Ohio App. 3d 221, 223; 540 N.E.2d 326 (Ohio 1988); Village of Bridgeport v. Bowen, 1995 Ohio App. LEXIS 3892, at *6 (Ohio Ct. App. 1995). In addition, it is significant that although the post-viability ban and the viability testing requirement lack scienter requirements, the ban on use of the D&X procedure does contain a scienter requirement.[37] Ohio courts have held if portions of a statute specify a culpable mental state, whereas other portions of the statute are silent as to the culpable mental state, this is a plain indication of an intent to impose strict liability in the latter sections or portions. *State v. Wac*, 68 Ohio St. 2d 84, 87; 428 N.E.2d 428 (Ohio 1981); *City of Brecksville v. Marchetti*, 1995 Ohio App. LEXIS 5164 (Ohio Ct. App. 1995). Based on the foregoing, this Court finds that the ban on post-viability abortions, and the viability testing requirement, "plainly indicate" an intention to create strict liability.

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[37] O.R.C. § 2919.15(B) provides: "No person shall knowingly perform or attempt to perform a Dilation and Extraction procedure upon a pregnant

Even if this were not the case, however, Ohio courts would be unable to import a recklessness requirement without, in effect, rewriting the statute. This is because the statute's standard of "reasonableness," which imposes criminal liability if a physician acts unreasonably in determining that a medical emergency exists, is a lower standard for incurring criminal liability, from the perspective of the actor, than the standard of "recklessness."[38] If courts were to import a recklessness requirement into the medical emergency definition per the above-quoted section 2901.21(B), physicians would no

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woman." (emphasis added). This demonstrates that the General Assembly knows how to include a scienter requirement when that is its intention.

[38] The difference between the two standards is most easily discernible in the area of tort law. As an example, a physician who commits medical malpractice may be found guilty of negligence if he acts unreasonably. If he acts recklessly, however, he may be found guilty of gross negligence, which is a more serious offense, and exposes the physician to a greater degree of liability. *See*, *e.g.*, *Gearhart v. Angeloff*, 17 Ohio App. 2d 143; 244 N.E.2d 802 (Ohio 1969) ("Punitive damages may be recovered in an action for negligence where such negligence is so gross as to show a reckless indifference to the rights and safety of other persons.") (quoting syllabus).

longer be liable if they acted unreasonably, i.e., negligently; instead, they would have to act recklessly in order to be liable. This would contradict the legislature's intent to create liability if a physician fails to act "in the exercise of reasonable medical judgment," and would amount to rewriting the statute, which courts may not do. Therefore, this Court concludes that a scienter requirement may not be imported into the definition of medical emergency.

On the basis of the foregoing, this Court concludes that the Plaintiffs have shown a substantial likelihood of demonstrating that the medical emergency exception in O.R.C. § 2919.16(F) is unconstitutional on two grounds: first, it appears to be vague, because both the definition of medical emergency, and the provisions imposing criminal (and civil) liability for violations of the post-viability ban and the viability testing requirement, lack scienter requirements; second, the requirement that a physician's determination be objectively reasonable--that is, reasonable to other physicians--would appear to create a chilling effect that would prevent physicians from performing post-viability abortions where, in their own best judgment, an abortion is necessary to preserve the life or health of the mother.

5. Second Physician Concurrence Requirement

If it is determined that a post-viability abortion is necessary to save the life of the mother, or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the mother, the physician who performs the abortion must comply with a number of conditions governing the performance of the abortion. One of these provisions requires that at least one other doctor concur, in writing, as to the necessity of the abortion:

> The determination of the physician who performs ... the abortion ... is concurred in by at least one other physician who certifies in writing that the concurring physician has determined, in good faith, in the exercise of reasonable medical judgment, and following a review of the available medical records of and any available tests [sic] results pertaining to the pregnant woman, that the abortion is necessary to prevent the death of the pregnant woman or a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman.

O.R.C. § 2919.17(B)(1)(b). Plaintiff argues that this requirement is unconstitutional because it undermines the physician's judgment, imposes unnecessary and cumbersome delays, and will be difficult to satisfy because few physicians will be willing to concur, in writing, to an abortion's necessity.[39]

In Doe v. Bolton, the Supreme Court struck down a Georgia statute which required a physician to obtain confirmation of his decision to perform an abortion, from two other doctors. The Court reasoned that this requirement interfered with the physician's clinical judgment and discretion:

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[39] The testimony by doctors who perform late-term abortions indicates that this may be a valid concern. Dr. John Doe Number One testified that it would be "virtually impossible" to find a second physician who would be willing to certify in writing that an abortion is necessary: "No one wants to involve themselves in the issue. I think ... whether it would be fear of personal harm, whether it would be fear of being ostracized, fear of picketing, who would want to involve themselves in this issue. It would be much easier to ignore it rather than to have your name on that chart." (Tr., 12/5, at 51).

> The statute's emphasis ... is on the attending physician's 'best clinical judgment that an abortion is necessary.' That should be sufficient. The reasons for the presence of the confirmation step in the statute are perhaps apparent, but they are insufficient to withstand constitutional challenge.... If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice.

410 U.S. at 199. This holding by the Supreme Court appears to govern the analysis of the concurrence requirement in this case, and Defendants have made no argument as to why it should not so apply. Accordingly, this Court finds that Plaintiff has demonstrated a substantial likelihood of success of showing that the second physician concurrence requirement in House Bill 135 is unconstitutional, because it impermissibly interferes with the physician's discretion.

Additionally, it appears to this Court that this requirement may be unconstitutional for the same reasons which render the medical emergency definition likely to be unconstitutional; to wit, the requirement that a second physician concur "in good faith [and] in the exercise of reasonable medical judgment" imposes criminal and civil liability on such concurring physicians who act according to their own best clinical judgment, without any criminal intent. This is likely to create a chilling effect which will deter physicians from concurring, in writing, that an abortion is medically necessary; this will chill the performance of abortions which are necessary to preserve the life or health of the mother. Accordingly, this Court finds that Plaintiff has demonstrated a substantial likelihood of success of showing that the second physician concurrence requirement in House Bill 135 is unconstitutional, because it is likely to chill the performance of post-viability abortions which are necessary to preserve the life or health of the mother.

6. Choice of Method Requirement

Under House Bill 135, another condition which must be satisfied by a doctor performing a post-viability abortion is the so-called "choice of method" requirement:

> The physician who performs ... the abortion terminates ... the pregnancy in the manner that provides the best opportunity for the unborn human to survive, unless that physician determines, in good faith and in the exercise of reasonable medical judgment, that the termination of the pregnancy in that manner poses a significantly greater risk of the death of the pregnant woman or a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman than would other available methods of abortion.

O.R.C. § 2919.17(B)(1)(d) (emphasis added). Plaintiff argues that the requirement that a particular method of abortion be used unless it would pose a significantly greater risk of harm to the woman, is unconstitutional, because it requires the physician to "trade off" the woman's health for that of the fetus.

In Colautti v. Franklin, 439 U.S. 379, 400 (1979) the Supreme Court held that a statute which "requires the physician to make a 'trade-off' between the woman's health and additional percentage points of fetal survival" posed serious ethical and constitutional difficulties.

Later, in Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 769 (1986), the Supreme Court invalidated a "choice of method" provision which was remarkably similar to the challenged provision in House Bill 135, reasoning that the words "significantly greater medical risk" required the woman to bear an additional, increased risk to her health, and so was unconstitutional. The provision at issue in Thornburgh read:

> Every person who performs or induces an abortion after an unborn child has been determined to be viable shall exercise that degree of professional skill, care and diligence ... and the abortion technique employed shall be that which would provide the best opportunity for the unborn child to be aborted alive unless, in the good faith judgment of the physician, that method or technique would present a significantly greater medical risk to the life or health of the pregnant woman .... Any person who intentionally, knowingly, or recklessly violates that provisions of this subsection commits a felony of the third degree.

476 U.S. at 768 n.13 (emphasis added). The only differences between this statute and the one at issue in the present case are: first, that the provision in Thornburgh allowed the physician to rely solely on his best clinical judgment, whereas the provision in House Bill 135 does not; second, that the statute in Thornburgh required a culpable mental state in order to impose criminal liability, whereas House Bill 135 does not require any criminal intent. The Thornburgh provision therefore seems far less egregious than that in

House Bill 135, which, because it does not allow the physician to rely solely on his or her best clinical judgment, and imposes criminal liability even if there were no criminal intent, seems likely to have a chilling effect on the physician's exercise of discretion in determining which abortion method may be used without causing a "significantly" greater risk to the woman's health. This chilling effect would negatively impact the woman's life and health. Accordingly, this Court finds that Plaintiff has demonstrated a substantial likelihood of success of showing that the choice of method provision in House Bill 135 is unconstitutional, because it will impermissibly interfere with the physician's exercise of discretion, to the detriment of the pregnant woman's health.

Given the similarity between the provision in Thornburgh and the challenged provision in this case, this Court further finds that Plaintiff has demonstrated a substantial likelihood of success of showing that the choice of method requirement is unconstitutional, because it "trades off" the health of the mother for that of the fetus, and requires her to bear an increased medical risk.

7. Second Physician Attendance Requirement

Another requirement in House Bill 135 pertaining to the provision of post-viability abortions requires that a second physician be present when the abortion is performed, to care for the fetus:

> The physician who performs ... the abortion has arranged for the attendance in the same room in which the abortion is to be performed ... of at least one other physician who is to take control of, provide immediate medical care for, and take all reasonable steps necessary to preserve the life and health of the unborn human immediately upon the unborn human's complete expulsion or extraction from the pregnant woman.

O.R.C. § 2919.17(B)(1)(e). Plaintiff also challenges the constitutionality of this provision.

The Supreme Court has considered similar provisions in two cases. In Planned Parenthood Ass'n of Kansas City v. Ashcroft, 462 U.S. 476, 485-86 (1983), the Supreme Court upheld a second physician attendance requirement because it served the state's compelling interest in preserving the life of the fetus. Although there was no clear medical emergency exception in that statute, the Court construed the requirement as allowing for an exception in medical emergencies. 462 U.S. at 485 n.8. In Thornburgh, however, the Court struck down a second physician attendance requirement, because it did not contain a valid medical emergency exception. 476 U.S. at 771. Therefore, the constitutionality of the second physician attendance requirement in House Bill 135 appears to depend upon the validity of the statute's medical emergency exception.

As discussed above, this Court has found that Plaintiff has demonstrated a substantial likelihood of success of showing that the medical emergency exception in House Bill 135 is unconstitutional, because it lacks a scienter requirement, and is thus vague, and because its objective reasonableness standard will chill physicians from determining that a medical emergency exists. For that reason, this Court finds that Plaintiff has also demonstrated a substantial likelihood of success of showing that the second physician attendance requirement in House Bill 135 is unconstitutional.[40]

8. Rebuttable Presumption of Viability

For purposes of the ban on post-viability abortions, House Bill 135 creates a rebuttable presumption "that an unborn child of at least twenty-four weeks of gestational age is viable." O.R.C. § 2919.17(C). The statute defines gestational age as "the age of an unborn human as calculated from the first day of the last menstrual period of a pregnant woman." O.R.C. § 2919.16(B).

Plaintiff challenges this requirement on three grounds. First, Plaintiff argues that a rebuttable presumption of viability impermissibly limits the physician's discretion to determine viability. Second, Plaintiff argues that because the last menstrual period (LMP) method of calculating gestational age generally produces an age that is two weeks earlier than the age from conception, the presumption actually attaches at twenty-two weeks, when fetuses are not viable, and so is necessarily invalid. Finally, Plaintiff argues that because the presumption can only be rebutted after the physician is arrested and prosecuted, it will chill physicians from determining that fetuses of a gestational age of twenty-four or more weeks are not viable, and will constitute an undue burden on the right to seek a pre-viability abortion.

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[40] In this Court's opinion, the chilling argument which applied to the second physician concurrence requirement would not apply to this requirement, which does not require the second physician to give a written endorsement of the abortion, and merely requires him or her to perform the arguably laudable role of caring for the fetus.

This Court declines to consider the likelihood of success of any of these arguments. Although the Supreme Court's decision in Webster v. Reproductive Health Services, 492 U.S. 490 (1989), indicates that it may be constitutionally permissible for a state to impose a rebuttable presumption of viability,[41] this Court finds it unnecessary to reach this issue at this time, because, as was discussed supra, Plaintiff has demonstrated a substantial likelihood of success of showing that the determination of non-viability in House Bill 135 is unconstitutionally vague, as the objective standard in that determination conflicts with the purely subjective standard in the statute's definition of viable in O.R.C. § 2919.16(L). If this Court determines, after a hearing on the merits, that the determination of non-viability is unconstitutional, then any portion of the statute which requires a physician to either determine viability, or rebut a presumption of viability, must, likewise, be invalidated.

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[41] In Webster, a five-member majority of the Supreme Court upheld a viability testing requirement that attached at the twentieth week of pregnancy. Although the challenged statute also imposed "what is essentially a presumption of viability at 20 weeks," Id. at 515, Justice O'Connor pointed out in her concurring opinion that the constitutionality of that presumption was not an issue before the Court. Id. at 526. Justice O'Connor did state, however, that, in her opinion, an argument that this presumption of viability impermissibly restricted the judgment of the physician would probably be unsuccessful. Id. at 527.

Accordingly, the Court finds it unnecessary to reach any of Plaintiff's arguments, in order to find that Plaintiff has demonstrated a substantial likelihood of success of showing that the rebuttable presumption of viability is unconstitutional, for the reason that the statute's mandated determination of non-viability is invalid.

E. Viability Testing Requirement

The third major portion of House Bill 135 creates a viability testing requirement at the twenty-second week of pregnancy, which must be complied with before an abortion after that time may be performed:

> Except as provided in [the medical emergency exception], no physician shall perform ... an abortion upon a pregnant woman after the beginning of her twenty-second week of pregnancy unless, prior to the performance [of] ... the abortion, the physician determines, in good faith and in the exercise of reasonable medical judgment, that the unborn human is not viable, and the physician makes that determination after performing a medical examination of the pregnant woman and after performing or causing the performing of gestational age, weight, lung maturity, or other tests of the unborn human that a reasonable physician making a determination as to whether an unborn human is or is not viable would perform or cause to be performed.

O.R.C. § 2919.18(A)(1). In addition to performing these tests, the physician may not perform the abortion "without first entering the determination ... and the associated findings of the medical examination and tests described ... in the medical records of the pregnant woman." § 2919.18(A)(2). The physician need not comply with either of these requirements if a medical emergency exists. § 2919.18(A)(3).

Violation of this section of the Act is a fourth degree misdemeanor. § 2919.18(B).

Although a viability testing requirement was upheld in Webster, 492 U.S. at 490, the viability testing requirement in House Bill 135 appears to be unconstitutional for two reasons. First, for the reasons given in an earlier part of this opinion, the statute's determination of non-viability appears to be unconstitutionally vague. Second, for the reasons also given in an earlier part of this opinion, the definition of medical emergency appears to lack a mens rea requirement, which creates vagueness, and also appears likely to create a chilling effect that would unconstitutionally jeopardize the life or health of pregnant women needing an abortion, due to its requirement that a physician's determination that a medical emergency exists be objectively reasonable.

Accordingly, Plaintiff has demonstrated a substantial likelihood of success of showing that the challenged viability testing requirement is unconstitutional, for two reasons. First, it lacks a valid medical emergency exception. Second, the definition of viable in O.R.C. § 2919.16(L), which applies to this viability testing requirement,[42] allows the physician to rely solely on his or her own best clinical judgment, whereas this mandated determination of non-viability also imposes a requirement that the physician's determination be

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[42] The definitions in O.R.C. § 2919.16 apply both to the post-viability ban in § 2919.17, and to the viability testing requirement in § 2919.18. If the definition is flawed, then a regulation or requirement based on that definition is also flawed.

objectively reasonable; this conflict creates an ambiguity which appears to render this portion of the Act unconstitutionally vague, because the physician has no clear guidance as to what standard will be applied in judging whether he or she is criminally and civilly liable.

III. Whether Issuance of an Injunction Will Save Plaintiff from Irreparable Injury

Having considered the substantial likelihood of Plaintiff's success on the merits, this Court now turns to the remaining prongs governing the issuance of a preliminary injunction. The second prong of the preliminary injunction standard requires the Court to make findings as to whether the issuance of an injunction is necessary to save the plaintiff from irreparable injury.

Importantly, Plaintiff Haskell has standing in this lawsuit not only to raise his own rights, but also to raise the rights of his patients. Therefore, this Court need not decide whether the harm which Plaintiff Haskell will suffer if prosecuted criminally or sued civilly under the Act, is irreparable. Instead, this Court will focus on the harm which will be suffered by his patients.

Both Jane Doe Number One and Jane Doe Number Two testified that they chose to terminate their pregnancies, late in the second trimester, after discovering that their unborn children had severe anomalies. If this Act had been in effect, either or both of these women may have been prevented from terminating their pregnancies, under either the provisions of the viability testing requirement, or the provisions of the post-viability ban. In both cases, the fetus may well have been determined to have been viable, and would not have been able to be aborted.

In this Court's opinion, the cost of being forced by the state to carry to term a child without a spine, or functioning kidneys, or with other such severe defects, is beyond description. It is difficult to imagine how horrible it would be to knowingly carry a child to term who is dying, or who has no reasonable chance of normal physical development.[43]

In addition, it is impossible to calculate the harm which would be suffered by a pregnant woman who, though she would prefer to try surgery or other methods to mitigate her unborn child's severe defects, is compelled by this ban on post-viability abortions--which only allows an abortion if her physical health is in danger--to terminate her pregnancy before the ban can apply to her, instead of taking measures to help her unborn child, because she feared the emotional and mental cost of carrying a child to term who had such severe defects. It is difficult to imagine a clearer example of irreparable harm, than is evidenced by these two scenarios.

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[43] Although it may seem that a child who was certain to die, and had no reasonable chance for normal development, would not be considered to be viable, the testimony in this case indicates otherwise. Dr. Harlan Giles, for example, testified that babies with certain chromosomal defects are considered to be viable "even though these children have no reasonable chance for normal mental motor development.... even though it's a very serious defect, [and] even though it usually leads to death in the nursery." (Tr., 11/13, at 236).

As for the harm suffered by pregnant women who are unable to terminate their pregnancies by means of the D&X procedure, Jane Doe Number Two testified that the procedure was helpful to her because it allowed her fetus to be aborted intact, which was necessary for the performance of an autopsy. After learning that the defect was not genetic, she and her husband had more children. Jane Doe Number One testified that the D&X procedure was much easier to endure than an earlier abortion performed by use of an induction procedure. In addition, this Court has held that Plaintiff has demonstrated a substantial likelihood of success of showing that the alternatives to the D&X procedure--induction methods, hysterotomies, and hysterectomies--are neither as safe to the mother's health, nor as available to women seeking non-therapeutic abortions. Pregnant women in this state who are unable to terminate their pregnancies by means of the D&X procedure may therefore suffer irreparable harm, either because other abortion methods are not as safe for their health, or because other abortion methods are not as available to them.

Based on the above, this Court concludes that a preliminary injunction would serve to prevent irreparable injury to the patients of Plaintiff Haskell.

IV. Whether Issuance of an Injunction Would Harm Others

The third prong of the preliminary injunction standard traditionally requires this Court to "balance the equities" in considering whether the harm to the Defendant resulting from issuing the injunction, would outweigh the harm to the Plaintiff resulting from denying the injunction.

As far as the Defendants' interests are concerned, a preliminary injunction will merely maintain the status quo while the constitutionality of this legislation is decided. The potential for irreparable injury to some of Plaintiff's patients has already been discussed; in addition, other pregnant women may be harmed by specific provisions of the Act. For example, the objective reasonableness standard in the medical emergency definition may chill the discretion of a pregnant woman's physician in determining that a medical emergency exists, to the detriment of her health. As another example, the apparent vagueness of the determination of non-viability may chill physicians from determining that certain fetuses are not viable, and, therefore, may place an undue burden in the path of a woman seeking a pre-viability abortion. In this Court's opinion, therefore, the harm to the patients whom Plaintiff represents, should the preliminary injunction be denied, would be greater than the harm to the Defendants, if the injunction were granted.

V. Whether Issuance of an Injunction Would Serve the Public Interest

The final prong of the preliminary injunction standard requires this Court to determine whether the issuance of an injunction would serve the public interest.

In this Court's opinion, the public interest is best served by a full and fair hearing on the merits of the constitutionality of this legislation, particularly in view of the fact that the Plaintiff has demonstrated a substantial likelihood of success of showing that numerous provisions in House Bill 135 are unconstitutional. Accordingly, the Court concludes that the public interest would be served by the issuance of a preliminary injunction.

VI. Conclusion/Conclusions of Law

To summarize, this Court has held that all four prongs of the preliminary injunction standard weigh in favor of granting a preliminary injunction, which enjoins enforcement of all provisions of House Bill 135. In addition, this Court has held:

(1) it has federal question jurisdiction, under 28 U.S.C. § 1331, over this constitutional challenge to a state statute,

(2) Plaintiff Haskell may seek pre-enforcement review of House Bill 135, and this lawsuit is therefore ripe;

(3) Plaintiff Haskell has standing to bring this action, and may assert both his own rights and the rights of his patients;

(4) the Salerno standard no longer applies to a facial challenge to pre-viability abortion regulations;

(5) the Salerno standard does not apply to a facial challenge to post-viability abortion regulations;

(6) although a state may proscribe most abortions subsequent to viability, the state may not take away a pregnant woman's right to have a post-viability abortion where, in appropriate medical judgment, such an abortion is necessary to preserve her life or health--accordingly, strict scrutiny should not be utilized in this analysis;

(7) Plaintiff has demonstrated a substantial likelihood of success of showing that the definition of "Dilation and Extraction procedure" in O.R.C. § 2919.15(A) is unconstitutional, because of vagueness;

(8) Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on use of the D&X procedure in § 2919.15(B) is unconstitutional, because the state may not ban an abortion procedure unless there are safe and available alternatives, and because this ban may chill the exercise of a woman's right to a pre-viability abortion;

(9) Plaintiff has demonstrated a substantial likelihood of success of showing that the ban on use of the D&X procedure does not serve the stated interest of preventing unnecessary cruelty to the fetus;

(10) Plaintiff has demonstrated a substantial likelihood of success of showing that the mandated determination of non-viability in § 2919.18(A)(1), as applied to the post-viability ban (§ 2919.17(A)(2)) and the viability testing requirement (§ 2919.18), is unconstitutional, because the objective

standard in that determination is inconsistent with the purely subjective standard in the definition of viable in § 2919.16(L);

(11) Plaintiff has demonstrated a substantial likelihood of success of showing that the definition of serious risk of the substantial and irreversible impairment of a major bodily function in § 2919.16(J), as it applies to one allowable exception to the ban on post viability abortions, in § 2919.17(A)(1), is unconstitutional, because its limitation to factors relating solely to physical health impermissibly restricts the physician's determination of whether an abortion is necessary to preserve the health of the pregnant woman;

(12) Plaintiff has demonstrated a substantial likelihood of success of showing that the definition of medical emergency in § 2919.16(F), as it applies to the post-viability ban (§ 2919.17) and the viability testing requirement (§ 2919.18), is unconstitutional, because it lacks a scienter requirement, and thus is vague, and because it does not allow the physician to rely on his or her own best clinical judgment that a medical emergency exists, and so may chill physicians from determining that a medical emergency exists even where necessary to preserve the pregnant woman's life or health;

(13) Plaintiff has demonstrated a substantial likelihood of success of showing that the second physician concurrence requirement in § 2919.17(B)(1)(b) is unconstitutional, because it impermissibly limits the primary physician's discretion, and because it may chill the performance of post-viability

abortions that are necessary to preserve the life or health of the mother;

(14) Plaintiff has demonstrated a substantial likelihood of success of showing that the choice of method requirement in § 2919.17(B)(1)(d) is unconstitutional, because it requires the woman to bear an increased medical risk, forces the physician to "trade off" the pregnant woman's health for that of the fetus, and impermissibly interferes with the physician's exercise of discretion, to the detriment of the pregnant woman's health;

(15) Plaintiff has demonstrated a substantial likelihood of success of showing that the second physician attendance requirement in § 2919.17(B)(1)(e) is unconstitutional, because the medical emergency exception appears to be unconstitutional;

(16) Plaintiff has demonstrated a substantial likelihood of success of showing that the rebuttable presumption of viability in § 2919.17(C) is unconstitutional, because the mandated determination of non-viability in House Bill 135 appears to be unconstitutional;

(17) Plaintiff has demonstrated a substantial likelihood of success of showing that the viability testing requirement in § 2919.18(A)(1) is unconstitutional, because the medical emergency definition appears to be unconstitutional, and because the mandated determination of non-viability appears to be unconstitutional.

This Court further concludes that the issuance of an injunction will prevent irreparable injury to the patients of Plaintiff Haskell, that such injury outweighs the injury which will be suffered by Defendants if this injunction is issued, and that the public interest would be served by the issuance of this preliminary injunction.[44]

WHEREFORE, based upon the aforesaid, this Court orders that the Plaintiff's Motion for a Preliminary Injunction be GRANTED, effective as of the filing of this opinion. Accordingly, Defendants, their employees, agents, and servants are preliminarily enjoined from enforcing any provision of House Bill 135. Having considered the issue of bond as is required by Rule 65 of the Federal Rules of Civil Procedure, this Court concludes that no bond should be required of the Plaintiff.

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[44] This Court adopts the findings set forth within this Opinion as its Findings of Fact, for purposes of Rule 52(a) of the Federal Rules of Civil Procedure. This Court finds support for its lack of separate findings of fact in the Supreme Court's holding "that there must be findings, stated either in the court's opinion or separately, which are sufficient to indicate the factual basis for the ultimate conclusion." *Kelley v. Everglades Drainage Dist.*, 319 U.S. 415, 422 (1943), *quoted with approval in B.F. Goodrich Co. v. Rubber Latex Prod., Inc.*, 400 F.2d 401, 402 (6th Cir. 1968); *see also Slanco v. United Counties*, No. 82-3115 (6th Cir. 1983) (allowing district court to adopt oral opinion as findings of fact and conclusions of law for purposes of Rule 52); *Craggett v. Bd. of Educ. of Cleveland City Sch. Dist.*, 338 F.2d 941 (6th Cir. 1964) (allowing district court to adopt written memorandum as findings of fact and conclusions of law for purposes of Rule 52).

However, this Court assures Counsel for the Plaintiff and the state Defendants that their detailed, proposed Findings of Fact and Conclusions of Law were thoroughly reviewed and form the basis of much of the discussion contained herein. This includes the submissions of the state Defendants which were not fully delivered to this Court's chambers, by facsimile, until 3:45 a.m., this date. In short, the diligent efforts of Counsel have not been in vain.

For purposes of completing the record, this Court also renders the following evidentiary rulings: Plaintiff's Exhibit 24 is admitted, for the limited purpose of showing the position of the American College of Obstetricians and Gynecologists on the federal Partial Birth Abortion Act of 1995, but not for the truth of the statements asserted therein. Plaintiff's Exhibit 25 is excluded, as hearsay.

Counsel listed below will note that a brief telephone conference will be held, between Court and Counsel, beginning at 4:00 p.m., Eastern time, on Friday, December 22, 1995, for the express purpose of determining further procedures to be followed in this litigation. Specifically, Counsel should be prepared to discuss whether they wish to proceed to trial upon the merits of the captioned cause, at a date in mid-1996, or whether, in the alternative, Defendants wish to take an immediate appeal of this decision to the Sixth Circuit Court of Appeals, pursuant to 28 U.S.C. § 1292(a)(1).

December 13, 1995

WALTER HERBERT RICE
UNITED STATES DISTRICT JUDGE

Copies to:

David C. Greer, Esq.
Alphonse A. Gerhardstein, Esq.
Sarah Poston, Esq.
Kathryn Kolbert, Esq.
Diane Richards, Esq.
Marilena Walters, Esq.
Elissa Cohen, Esq.
Chris Van Schaik, Esq.

THE WHITE HOUSE
WASHINGTON

February 28, 1996

The Honorable Henry J. Hyde
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I understand that the House is preparing to consider H.R. 1833, as amended by the Senate, which would prohibit doctors from performing a certain type of abortion. I want to make the Congress aware of my position on this extremely complex issue.

I have always believed that the decision to have an abortion should be between a woman, her conscience, her doctor, and her God. I strongly believe that legal abortions -- those abortions that the Supreme Court ruled in Roe v. Wade must be protected -- should be safe and rare. I have long opposed late-term abortions except, as the law requires, where they are necessary to protect the life of the mother or where there is a threat to her health. In fact, as Governor of Arkansas, I signed into law a bill that barred third trimester abortions except where they were necessary to protect the life or health of the woman, consistent with the Supreme Court's rulings.

The procedure described in H.R. 1833 is very disturbing, and I cannot support its use on an elective basis, where the abortion is being performed for non-health related reasons and there are equally safe medical procedures available. As I understand it, however, there are rare and tragic situations that can occur in a woman's pregnancy in which, in a doctor's medical judgment, the use of this procedure may be necessary to save a woman's life or to preserve her health. In those situations, the Constitution requires that a woman's ability to choose this procedure be protected.

I have studied and prayed about this issue, and about the families who must face this awful choice, for many months. I believe that we have a duty to try to find common ground: a resolution to this issue that respects the views of those -- including myself -- who object to this particular procedure, but also upholds the Supreme Court's requirement that laws regulating abortion protect both the life and the health of American women.

I have concluded that H.R. 1833 as drafted does not meet the constitutional requirements that the Supreme Court has imposed upon us, in Roe and the decisions that have followed it, to provide protections for both the life and the health of the mother in any laws regulating abortions.

I am prepared to support H.R. 1833, however, if it is amended to make clear that the prohibition of this procedure does not apply to situations in which the selection of the procedure, in the medical judgment of the attending physician, is necessary to preserve the life of the woman or avert serious adverse health consequences to the woman.

I urge the Congress to amend H.R. 1833 to ensure that it protects the life and the health of the woman, as the law we have been elected to uphold requires.

Sincerely,

Bill Clinton

Mrs. SCHROEDER. And, Mr. Chairman, I also want to go forward and say, let's talk about what *Roe* v. *Wade* says. *Roe* v. *Wade* talks about life and health of the mother. If we go back and look at the year 1920, 800 women died for every 100,000 births in America. In 1990, it was down to 10. While maternal morbidity is decreasing, we know pregnancy-related complications and deaths are still a public health concern. And we can't get complacent about safe motherhood.

I have all sorts of charts I was going to blow up. You know, when you look at what the Centers for Disease Control is telling us about the issue of safe motherhood in America, we're not there yet. And pregnancy is not a 9-month cruise for all women.

And so what *Roe* v. *Wade* has said is that the health and safety of the mother should also be taken into consideration. What so often happens is people want to focus on either the fetus or the mother. This is a difficult balancing act. And the question is, does Congress come in and weigh down on the scale on one side or the other, or do we trust the medical profession to be able to look at that and be able to make the best choice?

We're talking about women who suddenly have had things go wrong with their pregnancy. And the question we have is, do they get a second chance at motherhood? Should doctors be able to take that into their consideration as to which procedure they would choose? Does Congress know which is the best procedure in all of those instances where something has gone wrong late in term?

You know, I may get too emotionally involved in this, Mr. Chairman, and maybe that's because I know pregnancies are not a 9-month cruise. I had three of them. In one of them both children died, and in the third one I almost died. They gave me last rites and everything else. So I know that there can be very, very serious things go wrong. And I was very happy that the medical profession didn't have the Congress standing there looking over my doctor's shoulder and telling me, telling my minister, telling my family, what our choices were, and no matter what medical science said, forget it, Congress got to decide.

That's what we should be talking about here, because that's what the President talked about in his letter. That's what the Ohio court talked about in its decision that threw this kind of statute out, and I think that anything else that goes on in this hearing today is really very sad because we're just saying that women's health is secondary to a political agenda. And I don't think that women's health and their life should be secondary to any political agenda.

Mr. Chairman, I would also ask that the letter of Kathryn Kolbert on behalf of Dr. Haskell be entered into the record, explaining why he could not be here. And I would also ask that letters from Gail McMahon, who is the widow of Dr. McMahon; Dr. Herbert Jones's letter; Dr. William Rasbon's letter; Dr. Seymour Romney's letter, and Dr. Paul Blumenthal's letter all be placed in the hearing record at this time.

Mr. CANADY. Without objection.

[The information follows:]

Eve Surgical Centers
Medical Corporation

March 20, 1996

TESTIMONY OF GALE MCMAHON, R.N.

My name is Gale McMahon. I am the widow of Dr. James T. McMahon, and had worked with him for 26 years. I am a registered nurse with my training originally in the medical intensive care unit at County USC Medical Center in Los Angeles.

From the many years of our professional relationship, I learned of his truly sincere dedication to medicine. He wrote after medical school to his sister "...one must do what is meaningful or suffer the gravest consequences. I couldn't stand the emptiness of success on only a financial basis when I am sure that I can give and take more to and from this interesting world."

He found his meaning in the step-sister of medicine, abortion. His experience led to an even greater respect for women and their nurturing natures and ability to think of all involved. He believed them. My husband was a true intellectual, academically graduating cum laude from medical school, and technically developing a procedure to preserve the dignity and reproductive future of women in need.

My husband is no longer here to defend the women that need him so desperately, so I feel it necessary to speak in his stead. He believed in women deciding their futures, when nature had failed them. He worked daily with families that had to come to him, to choose the day that their baby would die. He offered them dignity and hope. The parents could still have a sense of control in a situation that was out of control.

We cry with the families over the loss and the hole they will experience in their lives. In return they share their future with us, by way of including us in their close circle of friends who they send the joyful birth announcement and pictures of their growing families, along with their heartfelt thanks for helping to get that far. Congress should feel as lucky as we have felt, by being able to allow families to decide.

Sincerely,

Gale McMahon, R.N.

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JOHNS HOPKINS
BAYVIEW MEDICAL CENTER

March 18, 1996

Representative Charles Canady
United States House of Representatives
Washington, D.C.

Dear Mr. Canady:

I am Dr. Paul Blumenthal, a Board-Certified Obstetrician-Gynecologist practicing at Johns Hopkins Bayview Medical Center. I am an Associate Professor of Gynecology and Obstetrics at The Johns Hopkins University and am the Medical Director of Planned Parenthood of Maryland. I am also a specialist in epidemiology and reproductive health care and am a Fellow of the American College of Obstetricians and Gynecologists. In addition, I am an advisor to the World Health Organization, and the United States Agency for International Development, on issues relating to safe motherhood, contraception and reproductive health care. As a result, I have traveled extensively for the Johns Hopkins Program in International Education in Reproductive Health, particularly in Africa and Southeast Asia, setting up programs to improve maternal health and access to safe and voluntary family planning services.

I ask you to oppose HR1833, a bill designed to undermine a woman's right to proper reproductive health care, including abortion, and to interfere with a physician's ability to make proper medical decisions based on his or her judgment.

In my capacity as an international advisor, I go to countries where access to abortion services is poor, where abortion is still illegal and where maternity wards continue to be filled with women suffering the effects of unsafe abortion. Many of them die. In fact, in many countries, the situation is similar to the way things were in the United States before safe and accessible abortion services were available; unsafe abortion is still the most common cause of maternal death. We believe that, in this country we have gotten beyond that point. We have recognized that women need and deserve access to safe abortion. It is thus our job to make *those* procedures safe, as well as to protect womens' lives during childbirth.

It is quite clear that this bill would reduce access to safe abortion and would define the doctors who perform them as criminals. There is actually no formally recognized medical procedure to which the term referred to in this bill applies; it is therefore vague and medically incorrect. None of my colleagues know or could actually state whether the procedures they now perform could be covered under this bill. One can only assume that by intimidating providers with the constant threat of criminal accusations, the intent is to frighten the medical community, the same community which swears an ancient oath to use its knowledge and skills to serve and protect the lives of its patients, from performing pregnancy terminations at all.

Proponents of the bill seem to be claiming that this will ban a particular procedure. However, as I noted, this procedure is not defined in such a way as to know exactly what it is that is being banned. However, even if it were clear, it would be unprecedented for a legislature to ban a *particular* procedure; essentially, to practice medicine from the house chamber without ever seeing a patient, understanding their needs and without knowing what physicians face on a day-to-day basis.

The practice of high quality medicine requires that, in order to accomplish a given treatment or therapy, physicians need to be knowledgeable about and be able to perform a variety of procedures. Planning such a procedure is done in consultation with the patient, based on the experience and training of the provider and the individual circumstances of the patient's condition. Sometimes, one plans to perform a certain surgical procedure, but, as a result of developments during the surgery and/or patient's condition, one must adapt and choose a different course or modify the procedure as originally planned. These decisions are often quite complex and mandate that physicians use their best professional and clinical judgment, most often, right on the spot. These are decisions which should be made by physicians and their patients alone. Indeed, when performing surgery there is no time for a call to the legislature, the supreme court, or anyone else in order to ascertain a statutory position, or to request a waiver. Physician and surgeons should be allowed to practice their art in accordance with time-honored peer review standards and with only the interests of the patient at heart.

This bill evokes an image of we physicians requiring that our attorneys be present in the operating room, to advise and counsel us at each step. If a procedure even appears to goes in a certain direction, we could be criminally charged. On the other hand, if we fail to use our best *medical* judgment, because of this law, they are exposed to charges of malpractice, negligence and would have violated both our own personal and professional standards, as well as the oath we have sworn for hundreds of years.

To be sure, discussing abortion procedures, or any other type of surgery, is often not pleasant. On the other hand, neither is it easy to discuss lethal fetal conditions like skeletal dysplasia. This is a group of genetic syndromes which result in the birth of infants who are destined to die within the first few minutes to hours of life, and whose only experience of life is that of suffocation as they gasp in an attempt to breathe.

Advances in prenatal detection may now allow a couple to know that this will be the fate of their wanted pregnancy. If a couple struggles with this information and then decide to terminate that pregnancy, it is my duty to help them, using the safest, most effective procedure I know. For these reasons and in order that physicians will always be able to put their patients' needs first, I urge you to reject HR1833.

Sincerely,

Paul D. Blumenthal, MD, MPH
Associate Professor of Gynecology and Obstetrics
Johns Hopkins University

Note: The opinions expressed here are those of Dr. Blumenthal and not necessarily those of the Johns Hopkins University. The Johns Hopkins Health System or the Johns Hopkins Bayview Medical Center.

WILLIAM K. RASHBAUM, M.D., P.C.
208 EAST 72ND STREET
NEW YORK, N. Y. 10021
TELEPHONE (212) 988-8300

The Honorable Charles Canady
United States House of Representatives
Washington, DC 20515-0912

March 19, 1996

Dear Representative Canady:

I write to you today to strongly urge your committee to reconsider HR #1833. I am a professor of Obstetrics and Gynecology at The Albert Einstein College of Medicine and The Cornell School of Medicine. I started performing and teaching Dilation and Evacuation techniques in 1978.

My colleagues and I have completed over 19,000 procedures since we began. We have done the D&X method that is under consideration in HR 1833 routinely since 1979. This procedure is only performed in cases of later gestational age.

To ban the D&X would only be making a very safe procedure more dangerous. Dilation and Evacuation requires surgical instruments that could result in rare but severe damage to the mother. The D&X procedure does not require the use of these instruments.

Outlawing the D&X *will* result in higher maternal health risks and mortality. The result to the fetus is the same - unfortunate but merciful termination regardless of method.

Please reconsider HR # 1833 and leave medical decisions to physicians who are equipped with the necessary knowledge and experience to make them.

Respectfully yours,

William K. Rashbaum, MD

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March 18, 1996

Representative Charles Canady
U.S. House of Representatives
Washington, D.C.

Dear Representative Canady:

The action of your House Subcommittee on the Constitution which would support the passage of HR 1833 is a tragic intrusion on the patient-doctor relationship. Such legislation would be glaringly inconsistent with the responsibility of physicians to practice sound, compassionate medicine. An unfortunate late diagnosis of a genetic or fetal malformation is not served by politically motivated intrusions.

In its simplest analysis, Congress is not trained to evaluate the safety and procedural details of any medical procedure. If the controversial issue of abortion and its treatment becomes a sounding board for the determination of the safety and efficacy of medical care, specifically the details of surgery and therapeutic measures and if procedures are criminalized because of power politics, it is conceivable that professionally sound medical and life saving measures could be banned without any physiologic or sound therapeutic basis.

Midtrimester abortions are rare, and unfortunately they occur because of limitations in diagnostic techniques and knowledge. Genetic disabilities which could result in stillborn or neonatal deaths or in some rare instances newborns who are doomed from the time of their birth to profound disabilities, having no quality of life, are not the subjects for Congressional solutions. The accepted therapeutic decisions carried out by well trained and knowledgeable physicians represent accepted, compassionate procedures that are in the best interests of the health, the family welfare and the life of an unfortunate woman diagnosed to have a tragic fetal malformation.

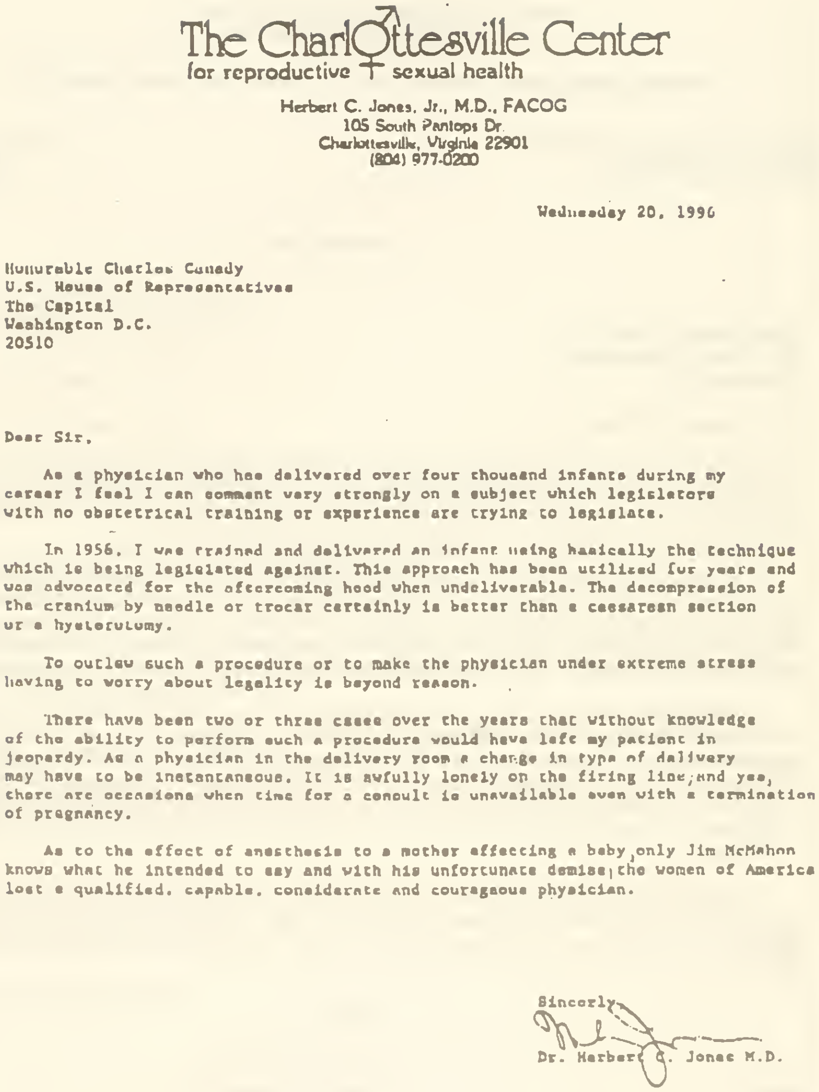
The legislation identified as HR 1833 usurps the physician medical responsibility at a time when we hear of the effort of reducing federal involvement in our personal lives. It is ironic that the medical profession is singled out as an exception. The health and welfare of a family involved in such a tragedy is not served by HR 1833.

Sincerely,

S L Romney

Seymour L. Romney, M.D.
Professor Emeritus

SLR/et
[illegible]



The Charlottesville Center
for reproductive sexual health

Herbert C. Jones, Jr., M.D., FACOG
105 South Pantops Dr.
Charlottesville, Virginia 22901
(804) 977-0200

Wednesday 20, 1996

Honorable Charles Canady
U.S. House of Representatives
The Capital
Washington D.C.
20510

Dear Sir,

As a physician who has delivered over four thousand infants during my career I feel I can comment very strongly on a subject which legislators with no obstetrical training or experience are trying to legislate.

In 1956, I was trained and delivered an infant using basically the technique which is being legislated against. This approach has been utilized for years and was advocated for the aftercoming head when undeliverable. The decompression of the cranium by needle or trocar certainly is better than a caesarean section or a hysterotomy.

To outlaw such a procedure or to make the physician under extreme stress having to worry about legality is beyond reason.

There have been two or three cases over the years that without knowledge of the ability to perform such a procedure would have left my patient in jeopardy. As a physician in the delivery room a change in type of delivery may have to be instantaneous. It is awfully lonely on the firing line; and yes, there are occasions when time for a consult is unavailable even with a termination of pregnancy.

As to the effect of anesthesia to a mother affecting a baby, only Jim McMahon knows what he intended to say and with his unfortunate demise, the women of America lost a qualified, capable, considerate and courageous physician.

Sincerly

Dr. Herbert C. Jones M.D.

C · R · L · P

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March 15, 1996

Representative Henry J. Hyde
Chairman, Committee on the Judiciary
House of Representatives
2110 Rayburn House Office Building
S. Capitol Street & Independence Ave., S.E.
Washington, DC 20515

Dear Representative Hyde.

I am writing on behalf of Martin Haskell, M.D., whom I currently represent in litigation challenging Ohio House Bill 135, which like H.R, 1833, bans certain methods of abortion. Because of the pending litigation, Dr. Haskell must decline your kind invitation to testify before the House Subcommittee on the Constitution on March 19, 1996.

As he informed the Senate when asked to testify on H.R. 1833 in November, 1995, Dr. Haskell has been the victim of physical harassment, blockades and threats by abortion opponents. He has also been the victim of a firebomb that extensively damaged one of his clinics. As a result, Dr. Haskell is refusing public and media appearances that may increase the risk of violence against him.

Most importantly, your March 8, 1996 invitation is clear that the Subcommittee intends that the prepared statements for hearings be put on the Internet. Dr. Haskell is extremely concerned that this practice may subject him to criminal liability for violation of 18 U.S.C. § 1462(c) as amended by Section 507 of the Telecommunications Act of 1996, a bill which you sponsored. Dr. Haskell notes that the law has never been enjoined. Since Dr. Haskell does receive income from his medical practice, his testimony could be considered advertising, something you explicitly said would be criminal. Moreover, discussion of the availability of abortion at his facilities, as well as the medical aspects of the procedure, may be a criminal violation under the explicit terms of the new

Telecommunications law.[1]

Nevertheless, Dr. Haskell has asked me to convey to you his strong opposition to H.R. 1833 and his belief that the federal government should not interfere in women's personal and private reproductive health decisions. While Dr. Haskell is mindful that his appearance before your Committee might clarify much of the misinformation currently circulating about his medical practice and about the purpose and effect of this legislation, he regrets that he will be unable to attend.

Very truly yours,

Kathryn Kolbert
Vice President

---

[1] The Act provides in pertinent part: Whoever . . . knowingly uses any . . . interactive computer service (as defined in section 230(e)(2) of the Communications Act of 1934), for carriage in interstate or foreign commerce -

* * *

> (c) any drug, medicine, article, or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; or any written or printed card, letter, circular, book, pamphlet, advertisement, or a notice of any kind giving information, directly or indirectly, where, how or of whom, or by what means any of such mentioned articles, matters, or things may be obtained or made; or

Whoever knowingly takes or receives from such . . . interactive computer service any matter or thing the carriage or importation of which is herein made unlawful-

Shall be fined under this title or imprisoned not more than five years, or both, for the first such offense and shall be fined under this title or imprisoned not more than ten years, or both, for each such offense thereafter.

Mr. CANADY. The gentlelady's time has expired.

We will now go to our first panel. First to testify today will be Congressman Tom Coburn, M.D., a distinguished colleague and member of the freshman class. In addition to representing the Second District of Oklahoma, Congressman Coburn is also a practicing family physician and still goes home to his district to deliver babies.

Congressman Coburn, we thank you for being here with us today. Without objection, your full statement will be made part of the already large record. And I would ask that you summarize your testimony in 5 minutes.

STATEMENT OF HON. TOM A. COBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Dr. COBURN. Thank you, Mr. Chairman. I find it interesting that—probably the most disappointing thing that I've experienced since I've come to Washington is that I had the belief that most people in this country, that if in fact you felt positively or strongly about an issue, even though others might disagree with you, that you would still try to use the truth to present your case. And, my disappointment in being a Member of Congress—and I find that this is not partisan at all, it tends to be on both sides of the aisle. But it's especially alarming to me as a physician, who—my primary agenda is women's health. I've delivered over 3,000 babies. I've delivered 50 babies since being a Member of Congress. I have, in fact, encountered every possible complication associated with pregnancies, both late term and early.

And what concerns me more than anything is that Members of Congress will, in fact, absolutely, intentionally distort the truth to put forth a cause. That's not partisan. That's on both sides of the aisle. It tells us what's wrong with our country today. It is a tremendous indication of the illness and the lack of moral rudder that we have.

I want to share with you that since I've been in Congress, and since this bill was debated, I've been asked by patients about the possible serious harm that could come to their baby because of anesthesia. This was not something prompted by me, but serious questions asked by my patients because of the misinformation that was put out surrounding this bill.

The point of what we should be about, whether we agree or disagree on this issue, should be truth. And that's what we should search to find. When we inflate and misguide to put forward a position, whether it's a justifiable or nonjustifiable position, we do great harm to this institution. But we also do even more harm to our country. And I would just say that this is one of the debates that I was ashamed to be associated with in the U.S. Congress, because, in fact, Members of this body made statements that they knew were not true, and did so trying to justify their position. No matter whether it's a position on abortion or any other thing, we should not allow that, and we should challenge that.

And so I'm glad that you're having this hearing because I think that the truth needs to be known by the American public that, in fact, we have great anesthesia in this country and that anesthesia is a safe, relatively safe procedure for women of all complications during pregnancy because of the tremendous science that's gone forward. And I know that you're going to hear that.

I would just say that I would be happy to answer any questions about my experience with anesthesia during pregnancy, the complications associated with it, and also, more importantly, the vast number of women who require anesthesia during their pregnancy with wonderfully positive outcome.

Thank you.

[The prepared statement of Dr. Coburn follows:]

PREPARED STATEMENT OF HON. TOM A. COBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Besides being a member of Congress, I am also a practicing physician who has delivered more than 3,000 babies.

Recently, one of my patients, an expectant mother, told me she was afraid of being given anesthesia to reduce her pain during delivery. She read that anesthesia is used to kill the fetus during a late-term abortion procedure known as the partial-birth abortion method.

This is completely inaccurate. In fact, Dr. Norig Ellison, President of the American Society of Anesthesiologists, stated before the Senate Judiciary Committee last fall that any suggestion that anesthesia kills the fetus has "absolutely no basis in scientific fact."

The fact is when general anesthesia is administered to the mother, only a portion of that anesthetic may reach the fetus, but hardly enough to cause any threat to the health or life of the fetus.

I was alarmed by this erroneous information because it could negatively impact the health of any pregnant woman who, fearing the consequences of anesthesia on her unborn child, may delay necessary and even life-saving medical procedures.

The misinformation is being spread by opponents of H.R. 1833, the Partial-Birth Abortion Ban Act, to make the procedure appear more humane.

Regardless of the motivations, this rhetoric is reckless and irresponsible.

Legislators and physicians must work together to ensure that the public receives accurate information so they can make educated decisions regarding health care. Others involved in making and influencing public policy should stick to truths and refrain from using inaccuracies to promote their viewpoint.

Afterall, this is not a pro-choice versus pro-life issue, but rather a medical issue that could have serious consequences on the health of a woman and her unborn child.

Mr. CANADY. Thank you, Doctor. I appreciate your testimony, and I share your frustration in general about problems that we see with people misrepresenting facts, and I would be the first to acknowledge that's not limited to one party or the other. It's not limited to the abortion issue.

I have found that it has been a particular problem in connection with this bill because we have seen one distortion after another. We started off hearing that there was no such thing as partial-birth abortion, that this sort of procedure was never performed. Then we heard, "Well, it's only performed occasionally." We had drawings of the procedure which were challenged. It was said that they were not accurate, that they did not depict the procedure. Then it was acknowledged even by a witness for the National Abortion Federation, "Well, they were technically accurate." So, we've seen, at every step of the debate along the way, we've seen that sort of distortion.

Of all the distortions, this is the most troubling distortion because this poses a direct threat to the health of women. And I think that it is very ironic that those who so frequently profess a preeminent concern for the health of women have been guilty of repeating this misinformation which poses a threat to the health of women even when they have been informed that it is not true, that it is not so. It's going to be interesting to see what takes place as the debate moves forward from this day. But I think that it certainly calls into question the credibility those who say that their first concern is the health of women, if they are willing to engage in this attempt to mislead and confuse for the—to derail this bill or to harm this bill, and, as a side effect, harm the health of women.

Let me just ask you, Doctor, if on the general subject here, if you believe that there is any legitimate health reason to partially deliver a live fetus before killing the fetus and completing the delivery, as specified in the Partial-Birth Abortion Ban Act.

Dr. COBURN. No, I don't. And, again, I'm not an abortionist, but what I do know about that is that is a procedure that is designed for the aid and speed of the abortionist and has nothing to do with the health or life of the mother. Any baby, with the exception of holoprosencephaly, which is a hydrocephalus, marked enlargement, can be delivered vaginally at any of the stages that that would be put forward in another way. And the information put out about the procedure in terms of dilation killing the baby or ruptured membranes killing the baby, it's just absolutely untrue. Spontaneous or direct amniotome, rupture of the membranes, can lead to the death of the fetus, but only after infection sets up or prolapse of the cord or some other complication associated with the procedure. But the procedure itself does not.

So, I've not seen any case—I have had a woman who has had a pregnancy with holoprosencephaly that did have a procedure done to save her life, but it was not this procedure. This procedure was not required to do that. So, in fact, many other methods are available when, in fact, the mother's life is under—and that is an exception in this bill anyway. So the fact is that there are many other alternatives that can be used to solve the problems of such a terrible presentation.

Mr. CANADY. In your practice, or in your professional knowledge, are you aware of any case in which anesthesia administered to a pregnant woman has caused the death of the child she's carrying?

Dr. COBURN. No.

Mr. CANADY. Thank you, Doctor.

Mr. Hyde, do you have any questions?

Mr. HYDE. I have no questions.

Mr. CANADY. Doctor, we thank you very much for being with us today.

Dr. COBURN. Thank you.

Mr. CANADY. We'll now move to our second panel. And on our second panel, we will hear testimony from four physicians who specialize in the area of anesthesiology. We're putting your name tags there, and if you'd come forward and take your seats, we'd appreciate it.

And as with the other—as is our custom, your full statements will be made a part of the record, without objection, and we would ask that you would please summarize your testimony in 5 minutes or less.

And, again, the subcommittee is very grateful for your taking the time to be with us today.

Dr. Norig Ellison is the president of the American Society of Anesthesiologists. He currently serves as the clinical director of the department of anesthesia at the University of Pennsylvania Hospital and is a professor and vice chair of the department of anesthesia at the University of Pennsylvania School of Medicine.

Following Dr. Ellison, we will hear from Dr. David Birnbach. Dr. David—Dr. Birnbach is the president-elect of the Society of Obstetric Anesthesia and Perinatology. Dr. Birnbach is also director of obstetric anesthesiology at St. Luke's Roosevelt Hospital Center at Columbia University.

Dr. David Chestnut is chairman of the department of anesthesiology at the University of Alabama-Birmingham Hospital. Dr. Chestnut is a professor in both the department of obstetrics and gynecology and the department of anesthesiology at the University of Alabama-Birmingham School of Medicine. He also served as editor of the medical textbook, "Obstetric Anesthesia: Principles and Practice."

The final witness on our second panel today will be Dr. Jean Wright. Dr. Wright is the medical director at Egleston Children's Hospital at Emory University. She is also an associate professor in the department of pediatrics and anesthesiology at Emory.

Again, thank you for being here. Dr. Ellison.

STATEMENT OF NORIG ELLISON, M.D., PRESIDENT, AMERICAN SOCIETY OF ANESTHESIOLOGISTS

Dr. ELLISON. Chairman Canady, members of the subcommittee, my name is Norig Ellison. I am the president of the American Society of Anesthesiologists, a professional society consisting of over 34,000 anesthesiologists and other scientists engaged or particularly interested in the medical practice of anesthesiology. I am also professor and vice chair of the department of anesthesia at the University of Pennsylvania School of Medicine in Philadelphia and a staff anesthesiologist at the hospital of the University of Pennsylvania.

I appear here today for one purpose and one purpose only, to take issue with the testimony of Dr. James T. McMahon before this subcommittee last June. According to his written testimony, of which I have a copy, Dr. McMahon stated that anesthesia given to the mother as part of dilation and extraction abortion procedure eliminates any pain to the fetus and that a medical coma is induced in the fetus causing, quote, "a neurologic fetal demise, or in lay terms, brain death," end quote.

I believe this statement to be entirely inaccurate. I am deeply concerned, moreover, that the widespread publicity given to Dr. McMahon's testimony may cause pregnant women to delay necessary, even life-saving medical procedures totally unrelated to the birthing process due to misinformation regarding the effect of anesthetics on the fetus. Annually, over 50,000 pregnant women are anesthetized for such necessary procedures. Although it is certainly true that some analgesic or anesthetic medication given to the mother will reach the fetus and perhaps provide some pain relief, it is equally true that pregnant women are routinely heavily sedated or anesthetized during the second or third trimester for the performance of a variety of necessary surgical procedures with absolutely no adverse effect on the fetus, let alone brain death. In my medical judgment, it would be necessary, in order to achieve neurologic demise of the fetus in a partial-birth abortion, to anesthetize the mother to such a degree as to place her own health in serious jeopardy.

As you are aware, Mr. Chairman, I gave similar testimony to a Senate committee on November 17. That testimony received wide circulation in anesthesiology circles and to a lesser extent in the lay press. You may be interested in the fact that, since my appearance, not one single anesthesiologist or other physician has contacted me to dispute my stated conclusion. Indeed, two eminent obstetric anesthesiologists and one equally eminent pediatric anesthesiologist appear here with me today testifying on their own behalf and not as ASA representatives. I am pleased to note that their testimony reaches the same conclusions that I have expressed.

I thank you for your attention, and I would be happy to respond to your questions.

[The prepared statement of Dr. Ellison follows:]

Prepared Statement of Norig Ellison, M.D., President, American Society of Anesthesiologists

Chairman Canady, members of the Subcommittee. My name is Norig Ellison, M.D., I am the President of the American Society of Anesthesiologists (ASA), a national professional society consisting of over 34,000 anesthesiologists and other scientists engaged or specially interested in the medical practice of anesthesiology. I am also Professor and Vice-Chair of the Department of Anesthesiology at the University of Pennsylvania School of Medicine in Philadelphia and a staff anesthesiologist at the Hospital of the University of Pennsylvania.

I appear here today for one purpose, and one purpose only: to take issue with the testimony of James T. McMahon, M.D., before this Subcommittee last June. According to his written testimony, of which I have a copy, Dr. McMahon stated that anesthesia given to the mother as part of dilation and extraction abortion procedure eliminates any pain to the fetus and that a medical coma is induced in the fetus, causing a "neurological fetal demise", or—In lay terms—"brain death."

I believe this statement to be entirely Inaccurate. I am deeply concerned, moreover, that the widespread publicity given to Dr. McMahon's testimony may cause pregnant women to delay necessary, even lifesaving, medical procedures, totally unrelated to the birthing process, due to misinformation regarding the effect of anesthetics on the fetus. Annually over 50,000 pregnant women are anesthetized for such necessary procedures.

Although it is certainly true that some general analgesic medications given to the mother will reach the fetus and perhaps provide some pain relief, It Is equally true that pregnant women are routinely heavily sedated during the second or third trimester for the performance of a variety of necessary surgical procedures with absolutely no adverse effect on the fetus, let alone death or "brain death." In my medical judgment, it would be necessary—in order lo achieve "neurological demise" of the fetus in a "partial birth" abortion—to anesthetize the mother to such a degree as to place her own health in serious jeopardy.

As you are aware, Mr. Chairman, I gave the same testimony to a Senate committee four months ago. That testimony received wide circulation In anesthesiology circles and to a lesser extent in the lay press. You may be interested in the fact that since my appearance, not one single anesthesiologist or other physician has contacted me to dispute my stated conclusions. Indeed, two eminent obstetric anesthesiologists appear with me today, testifying on their own behalf and not as ASA representatives. I am pleased to note that their testimony reaches the same conclusions that I have expressed.

Thank you for your attention. I am happy to respond to your questions.

Mr. CANADY. Thank you, Dr. Ellison. Dr. Birnbach.

STATEMENT OF DAVID J. BIRNBACH, M.D., DIRECTOR OF OBSTETRIC ANESTHESIOLOGY, ST. LUKE'S–ROOSEVELT HOSPITAL CENTER

Dr. BIRNBACH. Mr. Chairman, members of the subcommittee, my name is David Birnbach, M.D., and I am presently director of obstetric anesthesiology at St. Luke's-Roosevelt Hospital Center, which is a teaching hospital of Columbia University College of Physicians and Surgeons in New York City. I am also president-elect of the Society for Obstetric Anesthesia and Perinatology, which is the society which represents my subspecialty.

I am here today to take issue with the previous testimony before committees of the Congress that suggest that anesthesia causes fetal demise. I believe that I am qualified to address this issue because I am a practicing obstetric anesthesiologist. Since completing my anesthesiology and obstetric anesthesiology training at Harvard University, I've administered analgesia to more 5,000 women in labor and anesthesia to over 1,000 women undergoing cesarean section.

I have also provided anesthesia to approximately 200 patients who were carrying fetuses of less than 30 weeks' gestation, and who needed emergency, nonobstetric surgery during pregnancy. These operations have included appendectomies, gall bladder surgeries, orthopedic procedures, uterine and ovarian procedures including removal of malignant tumors, breast surgery, neurosurgery, and major cardiac surgery. The anesthetics which I have administered have included general, epidural, spinal, and local. The patients have included both healthy patients as well as very sick pregnant patients. Although I often use spinal and epidural anesthesia, I also administer general anesthesia, and, on occasion, I have needed to administer, quote, unquote, "huge doses of general anesthesia" in order to allow the surgeons to perform cardiac or neurosurgery.

In addition, I believe that I am especially qualified to discuss the effect of maternally-administered anesthesia on the fetus because I am one of only a handful of anesthesiologists who has administered anesthesia to a pregnant patient undergoing in utero fetal surgery which allowed me to watch the fetus as I administered general anesthesia to the mother. A review of the experiences that my associates and I had while administering general anesthesia to a mother while a surgeon operated on the fetus was published in the Journal of Clinical Anesthesia.

Safe doses of anesthesia to the mother certainly did not cause fetal demise when used for these operations. Despite my extensive experience with providing anesthesia to the pregnant patient, I have never witnessed a case of fetal demise that could be attributed to an anesthetic. Although some drugs which we administered to the mother may cross the placenta and affect the fetus, in my medical judgment, fetal demise is definitely not a consequence of a properly-administered anesthetic. In order to cause fetal demise, it would be necessary to give the mother dangerous and life-threatening doses of anesthesia. This is not the way we practice anesthesiology in the United States.

Mr. Chairman, I am deeply concerned that the previous congressional testimony and the widespread publicity that has been given this issue will cause unnecessary fear and anxiety in pregnant patients and may cause some to unnecessarily delay emergency surgery.

As an example, several newspapers have turned this into a quote, unquote, "a controversy" and have said that fetal demise occurs after anesthesia. Evidence that patients are still receiving this misinformation regarding fetal effects of anesthesia can be seen by review of an article that a pregnant patient brought into me on labor and delivery last week from Marie Claire magazine. And she highlighted a line that says, "the mother is put under general anesthetic which reaches the fetus through her bloodstream. By the time the cervix is sufficiently dilated, the fetus is overdosed on the anesthetic and is brain dead." Now this patient came in saying, "Is that the kind of anesthesia you're giving me?"

Despite the previous testimony of Dr. Ellison, I have yet to see an article in the lay press that states in no uncertain terms that anesthesia when used properly does not harm the fetus.

This supposed controversy regarding the effects of anesthesia on the fetus must be finally and definitely put to rest. There is absolutely no scientific or clinical evidence that a properly-administered maternal anesthetic causes fetal demise. To the contrary, there are hundreds of scientific articles which demonstrate the fetal safety of currently used anesthetics.

In conclusion, I would like to say that I believe that I have a responsibility as a practicing obstetric anesthesiologist to refute any testimony that suggests that maternally-administered anesthesia causes fetal demise. Pregnant women must get the message that, should they need anesthesia for surgery or analgesia for labor, that they may do so without worrying about the effects on their unborn child.

Thank you. I'm happy to respond to your questions.

[The prepared statement of Dr. Birnbach follows:]

PREPARED STATEMENT OF DAVID J. BIRNBACH, M.D., DIRECTOR OF OBSTETRIC ANESTHESIOLOGY, ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

Mr. Chairman, Members of the Subcommittee, my name is David Birnbach, M.D. and I am presently the Director of Obstetric Anesthesiology at St. Luke's-Roosevelt Hospital Center, a teaching hospital of Columbia University College of Physicians and Surgeons in New York City. I am also president-elect of the Society for Obstetric Anesthesia and Perinatology, the society which represents my sub specialty.

I am here today to take issue with the previous testimony before committees of the Congress that suggests that anesthesia causes fetal demise. I believe that I am qualified to address this issue because I am a practicing obstetric anesthesiologist. Since completing my anesthesiology and obstetric anesthesiology training at Harvard University, I have administered analgesia to more than five thousand women in labor and anesthesia to over a thousand women undergoing cesarean section. Although the majority of these cases were at full term gestation, I have provided anesthesia to approximately 200 patients who were carrying fetuses of less than 30 weeks gestation and who needed emergency non-obstetric surgery during pregnancy. These operations have included appendectomies, gall bladder surgeries, numerous orthopedic procedures such as fractured ankles, uterine and ovarian procedures (including malignant tumor removal), breast surgery, neurosurgery, and cardiac surgery.

The anesthetics which I have administered have included general, epidural, spinal and local. The patients have included healthy as well as very sick pregnant patients. Although I often use spinal and epidural anesthesia in pregnant patients, I also administer general anesthesia to these patients and, on occasion, have needed to administer huge doses of general anesthesia in order to allow surgeons to perform cardiac surgery or neurosurgery.

In addition, I believe that I am also especially qualified to discuss the effect of maternally-administered anesthesia on the fetus, because I am one of only a handful of anesthesiologists who has administered anesthesia to a pregnant patient undergoing in-utero fetal surgery, thus allowing me to watch the fetus as I administered general anesthesia to the mother. A review of the experiences that my associates and I had while administering general anesthesia to a mother while a surgeon operated on her unborn fetus was published in the Journal of Clinical Anesthesia vol. 1, 1989, pp. 363–367. In this paper, we suggested that general anesthesia provides several advantages to the fetus who will undergo surgery and then be replaced in the womb to continue to grow until mature enough to be delivered. Safe doses of anesthesia to the mother most certainly did not cause fetal demise when used for these operations.

Despite my extensive experience with providing anesthesia to the pregnant patient, I have never witnessed a case of fetal demise that could be attributed to an anesthetic. Although some drugs which we administer to the mother may cross the placenta and affect the fetus, in my medical judgment fetal demise is definitely not a consequence of a properly administered anesthetic. In order to cause fetal demise it would be necessary to give the mother dangerous and life-threatening doses of anesthetics. This is not the way we practice anesthesiology in the United States.

Mr. Chairman, I am deeply concerned that the previous congressional testimony and the widespread publicity that has been given this issue will cause unnecessary fear and anxiety in pregnant patients and may cause some to unnecessarily delay emergency surgery. As an example, several newspapers across the U.S. have stated that anesthesia causes fetal demise. Because this issue has been allowed to become a "controversy" several of my patients have recently expressed concerns about anesthesia, having seen newspaper or heard radio or television coverage of this issue. Evidence that patients are still receiving misinformation regarding the fetal effects of maternally administered anesthesia can be seen by review of an article that a pregnant patient recently brought with her to the labor and delivery floor. In last month's edition of Marie Claire, a magazine which many of my pregnant patients read, an article about partial birth abortion states "The mother is put under general anesthetic, which reaches the fetus through her bloodstream. By the time the cervix is sufficiently dilated, the fetus has overdosed on the anesthetic and is brain-dead." These incorrect statements continue to find their way into newspapers and magazines around the country. Despite the previous testimony of Dr. Ellison, I have yet to see an article that states, in no uncertain terms, that anesthesia when used properly does not harm the fetus. This supposed controversy regarding the effects of anesthesia on the fetus must be finally and definitively put to rest.

In order to address this complex issue, I believe that it is necessary to comment on three of the statements which have recently been made to the Congress.

I) Dr. James McMahon, now deceased, testified that anesthesia causes neurologic fetal demise.

II) Dr. Lewis Koplick supported Dr. McMahon and stated "I am certain that anyone who would call Dr. McMahon a liar is speaking from ignorance of abortions in late pregnancy and of Dr. McMahon's technique and integrity."

III) Dr. Mary Campbell of Planned Parenthood has addressed this issue by writing the following: "Though these doses are high, the incremental administration of the drugs minimizes the probability of negative outcomes for the mother. In the fetus, these dosage levels may lead to fetal demise (death) in a fetus weakened by His own developmental anomalies."

My responses to these statements are as follows:

1. There is absolutely no scientific or clinical evidence that a properly administered maternal anesthetic causes fetal demise. To the contrary, there are hundreds of scientific articles which demonstrate the fetal safety of currently used anesthetics.
2. Dr. Koplick has stated that the "massive" doses used by Dr. McMahon are responsible for fetal demise. This again, is incorrect and there is no scientific or clinical data to support this allegation. I have personally administered "massive" doses of narcotics to intubated critically ill pregnant patients who were being treated in an intensive care unit. I am pleased to say that the fetuses were born alive and did well.
3. Dr. Campbell has described the narcotic protocol which Dr. McMahon had used during his D&X procedures: it includes the administration of Midazolam (1040 mg) and Fentanyl (900–2500 μg). Although there is no evidence that this massive dose will cause fetal demise, there is clear evidence that this excessive dose could cause maternal death. These doses are far in excess of any anesthetic that would be used by an anesthesiologist and even if they were incrementally given over a two to three hour period these doses would in all probability cause

enough respiratory depression of the mother, to necessitate intubation and/or assisted respiration. Since Dr. McMahon can not be questioned regarding his "heavy handed" anesthetic practice, I am unable to explain why he would willingly administer such huge amounts of drugs. If he did indeed administer 2500 μg of fentanyl and 40 mg of midazolam to a patient in a clinic, without an anesthesiologist present, he was definitely placing the mother's life at great risk.

In conclusion, I would like to say that I believe that I have a responsibility as a practicing obstetric anesthesiologist to refute any and all testimony that suggests that maternally administered anesthesia causes fetal demise. It is my opinion that in order to achieve that goal one would need to administer such huge doses of anesthetic to the mother as to place her life at jeopardy. Pregnant women must get the message that should they need anesthesia for surgery or analgesia for labor, they may do so without worrying about the effects on their unborn child.

Thank you for your attention. I am happy to respond to your questions.

Mr. CANADY. Thank you, Dr. Birnbach. Dr. Chestnut.

STATEMENT OF DAVID H. CHESTNUT, M.D., CHAIRMAN, DEPARTMENT OF ANESTHESIOLOGY, UNIVERSITY OF ALABAMA AT BIRMINGHAM

Dr. CHESTNUT. Mr. Chairman, members of the subcommittee, my name is David Chestnut. I am professor and chair of the department of anesthesiology and also a professor of obstetrics and gynecology at the University of Alabama School of Medicine. I am grateful for the opportunity to testify this morning on the effects of anesthesia administered to a mother during a partial-birth abortion.

Some proponents of this procedure have stated that the fetus dies of an overdose of anesthesia given to the mother and that the anesthesia induces fetal brain death in a matter of minutes. This is nonsense. There is no scientific basis for these claims.

As many as 75,000 pregnant women undergo anesthesia and surgery each year in the United States. A large number of these procedures are performed during the second and third trimesters of pregnancy. The vast majority of these women subsequently deliver a healthy baby.

In his description of dilation and extraction for late second-trimester abortion, Dr. Martin Haskell stated that he administers 1 percent lidocaine as the standard anesthesia. The fetus is unaffected by clinical does of local anesthetic administered to the mother. In the United States, most newborn babies are exposed to local anesthetic drugs during labor and delivery. These infants cannot be distinguished from newborn infants not exposed to local anesthetics. Rational use of local anesthetic drugs does not affect the fetus.

Dr. Lewis Koplik stated that he gives the mother small doses of Versed and fentanyl during performance of second-trimester abortion. In the United States, general anesthesia is administered to approximately 20 percent of women who undergo cesarean section. Administration of anesthetic drugs in doses larger than those described by Dr. Koplik has little effect on the fetus. Some of these infants exhibit transient, mild somnolence at delivery, but by 5 minutes of life, these infants typically cannot be distinguished from those infants whose mothers did not receive general anesthesia.

Dr. Koplik suggested that Dr. McMahon administered larger doses of Versed and fentanyl. Dr. Mary Campbell stated that this regimen is the drug combination most frequently used for late-term D&X abortion.

My comments are sevenfold. One, it is unlikely that a physician who is not trained as an anesthesiologist would give such large dose of Versed and fentanyl to any patient.

Two, it is unlikely that any physician would give such large doses of Versed and fentanyl to any patient in an outpatient setting. Administration of these doses of Versed and fentanyl would place the mother at risk for respiratory arrest.

Three, administration of these large doses of Versed and fentanyl would not result in fetal death or fetal neurologic demise unless there was serious compromise of the mother's health. Stated another way, these doses of Versed and fentanyl would not kill the fetus unless the mother was killed or injured first.

Four, administration of these drugs may provide some degree of fetal pain relief, but the extent to which this renders any procedure pain free is unknown. Obstetricians observe fetal withdrawal responses during performance of invasive procedures in utero. These responses suggest that the fetus is capable of experiencing pain even during the second trimester of pregnancy.

Five, Dr. Campbell stated that administration of large doses of Versed and fentanyl depress fetal respirations. This is irrelevant because the fetus does not depend on his or her respiratory efforts to maintain oxygenation.

Six, Dr. Campbell stated that administration of these doses of drugs preclude fetal respiration afterward. This need not affect neonatal outcome. After delivery, the physician provides respiratory support and reverses the narcotic effect with naloxone.

Seven, I am concerned regarding the suggestion that any physician might deliberately give any patient an overdose of anesthetic drugs. Such practice clearly would endanger the life of the mother.

In summary, these false claims regarding the effects of maternal anesthesia on the fetus may cause some pregnant women to delay necessary and even life-saving surgery during pregnancy. Further, these false claims may prompt other women to deny themselves adequate pain relief during labor and delivery.

Mr. Chairman, anesthesia during pregnancy is safe for the mother and the baby.

I will be happy to respond to your questions.

[The prepared statement of Dr. Chestnut follows:]

PREPARED STATEMENT OF DAVID H. CHESTNUT, M.D., CHAIRMAN, DEPARTMENT OF ANESTHESIOLOGY, UNIVERSITY OF ALABAMA AT BIRMINGHAM

My name is David H. Chestnut, M.D. I am Professor and Chairman of the Department of Anesthesiology at the University of Alabama at Birmingham. I am also Professor of Obstetrics and Gynecology at that institution. After graduating from the University of Alabama School of Medicine, I completed residencies in both anesthesiology and obstetrics and gynecology at Duke University Medical Center. For ten years I served on the faculty of the Departments of Anesthesia and Obstetrics and Gynecology at the University of Iowa College of Medicine. I assumed my present position in April, 1994. I am pleased to testify this morning on the effects of anesthesia administered to a mother during a partial-birth abortion.

Estimates of the incidence of non obstetric surgery performed during pregnancy range from 0.75% to 2%. Thus, as many as 75,000 pregnant women undergo anesthesia and surgery each year in the United States.[1] A large number of these procedures are performed during the second and third trimesters of pregnancy. Examples of commonly performed procedures include laparoscopy, appendectomy, cholecystectomy, and removal of malignant and nonmalignant tumors (e.g., thyroid nodule, breast cancer). In some cases, major surgery is necessary to alleviate life-threatening maternal cardiovascular or neurosurgical conditions. In many cases, postponement of surgery until the completion of pregnancy would compromise the mother's health.

Some proponents of partial birth abortion have claimed that administration of anesthesia to the mother results in fetal death. This is nonsense. Administration of anesthesia to the mother rarely results in fetal injury or death. Rather, the vast majority of women who undergo anesthesia for surgery during the second or third trimester of pregnancy subsequently deliver a healthy baby.

In his detailed description of dilation and extraction for late second trimester abortion, Dr. Martin Haskell stated that he administers 1% lidocaine with epinephrine intracervically as the standard anesthesia. Lidocaine is a local anesthetic that blocks neuronal impulses locally. Although it is absorbed into the systemic circulation, it does not result in substantial systemic effect. (That is, it does not provide significant sedation or systemic analgesia.) Lidocaine and other local anesthetics cross the placenta and enter the fetal circulation. However, fetal blood concentrations of local anesthetic typically are less than maternal blood concentrations. More important, the fetal central nervous system is unaffected by clinical doses of local anesthetic administered to the mother. Maternal administration of a local anesthetic does not result in fetal sedation, analgesia. or anesthesia. In the United States, most newborn infants are exposed to one or more local anesthetic drugs during labor and delivery. At delivery, these infants cannot be distinguished from newborn infants *not* exposed to local anesthetics during labor and delivery.

Dr. Haskell stated that he injects 12 ml of 1% lidocaine intracervically. This dose is approximately 25% of the dose of lidocaine required for administration of epidural anesthesia for cesarean section. Yet even these larger doses of lidocaine do not adversely affect the fetus. Rational use of local anesthetic drugs does not affect the fetus.

Dr. Haskell also described the nasal administration of nitrous oxide/oxygen analgesia. This technique would be expected to result in modest maternal sedation and would have little effect on the fetus. Dr. Haskell stated that patients with minimal bleeding are encouraged to walk within 30 minutes of the completion of the procedure. This confirms that his patients do not experience substantial sedation during the procedure.

In a letter to Senator Barbara Boxer (dated December 5, 1995), Dr. Lewis H. Koplik commented on earlier claims made by Dr. James McMahon. Dr. Koplik described his method of providing sedation and analgesia during second trimester dilation and evacuation (D&E) procedures. He stated that he gives 2 mg of Versed™ (midazolam) and 25, μg of fentanyl to the mother. Both Versed™ and fentanyl cross the placenta and enter the fetal circulation. However, these doses would be expected to result in modest maternal sedation and to have little effect on the fetus. Clearly these doses would not result in fetal death, and it is unlikely that these doses would result in substantial fetal sedation or analgesia. In the United States, approximately 20% of women who undergo cesarean section receive general anesthesia. Administration of hypnotic and analgesic drugs—in doses larger than those described by Dr. Koplik—results in little effect on the fetus. Some of these infants exhibit transient, mild somnolence at delivery, but by five minutes of life, these infants typically cannot be distinguished from those infants whose mothers did not receive general anesthesia.[2]

Dr. Koplik suggested that Dr. McMahon administered 10 to 40 mg of Versed™ and 900 to 2500 μg of fentanyl. In another letter to Senator Boxer, Dr. Mary Campbell stated that this regimen is "the drug combination most frequently used" for "late-term D&X abortion." My comments are six-fold:

> It is unlikely that a physician who is not trained as an anesthesiologist would give such large doses of Versed™ and fentanyl to *any* patient.
>
> It is unlikely that any physician—including an anesthesiologist—would give such large doses of Versed™ and fentanyl to any patient in an outpatient setting. Administration of these doses of Versed™ and fentanyl would likely require placement of an endotracheal tube in the mother and prolonged support of the mother's ventilation and oxygenation.
>
> Administration of these large doses of Versed™ and fentanyl would not result in fetal do or fetal neurologic demise unless there was serious compromise of the mother's ventilation, oxygenation, and circulation. Stated another way, these doses of Versed™ and fentanyl would not kill the fetus unless the mother was killed or injured first.
>
> Administration of these large doses of Versed™ and fentanyl would not consistently result in total analgesia/anesthesia for the fetus. Although it is true that analgesic drugs given to the mother cross the placenta, enter the fetal circulation, and perhaps provide some degree of pain relief, the extent to which this renders any procedure pain-free is unknown. Maternal fetal medicine spe-

cialists observe fetal withdrawal responses during performance of invasive procedures (e.g., needle sticks) in utero. These withdrawal responses suggest that the fetus is capable of experiencing pain—even during the second trimester of pregnancy. Very preterm infants (e.g., 24 weeks' gestation) demonstrate withdrawal responses to painful stimuli after delivery. Physicians at the University of California, San Francisco have performed a variety of surgical procedures on human fetuses in utero. Despite the administration of general anesthesia to the mother, these physicians have given additional fentanyl directly to the fetus at surgery, in order to increase the likelihood that the fetus would not experience pain during surgery.[3]

Dr. Campbell stated that administration of large doses of Versed™ and fentanyl depress fetal respirations. This is irrelevant, because the fetus does not depend on his/her own respiratory efforts to maintain ventilation/oxygenation in utero. Rather, fetal oxygenation depends on maintenance of an intact uteroplacental and umbilical circulation, which is unaffected by administration of Versed™ and fentanyl.

Dr. Campbell stated that administration of these doses of drugs "preclude fetal respiration afterward." This need not affect neonatal outcome. When a newborn infant has respiratory depression secondary to maternal administration of a narcotic drug, the physician provides respiratory support (i.e., bag and mask ventilation or endotracheal intubation) and reverses the narcotic effect with naloxone.

In her "fact sheet," Dr. Campbell stated: "The fetus dies of an overdose of anesthesia given to the mother intravenously." She further stated: "This induces brain death in the fetus in a matter of minutes." There is no scientific basis for these claims. Further, I am concerned over the suggestion that any physician might deliberately give any patient an "overdose" of analgesic/anesthetic drugs. Such practice would clearly endanger the life of the mother.

In summary, these false claims regarding the effects of maternal anesthesia on the fetus may cause some pregnant women to delay necessary and perhaps even life-saving surgery during pregnancy. Further, these false claims may prompt other women to deny themselves adequate pain relief during labor and vaginal or cesarean delivery. In almost all cases, anesthesia does not kill the fetus unless the mother is killed or seriously injured first. Clinical administration of local anesthetic drugs has negligible effect on the fetus. Administration of either small or large doses of Versed™ and fentanyl does not result in fetal death or fetal neurologic injury. I am skeptical that any physician in the United States would knowingly administer 10 to 40 mg of Versed™ and 900 to 2500 µg of fentanyl for an abortion procedure. Finally, it is unlikely that these doses consistently abolish all fetal pain.

I will be happy to respond to your questions.

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Mr. CANADY. Thank you, Doctor. Dr. Wright.

STATEMENT OF JEAN A. WRIGHT, M.D., MEDICAL DIRECTOR, EGLESTON CHILDREN'S HOSPITAL, EMORY UNIVERSITY

Dr. WRIGHT. Mr. Chairman and members of the subcommittee, my name is Jean Wright, and I am an associate professor of pediatrics and anesthesia at Emory School of Medicine, and I've been a practicing physician since 1983. My testimony will focus on three parts. First, the developmental aspects of pain in the neonate. Second, the increased sensitivity of preterm infants to pain compared to term or older children. And, thirdly, the effects of maternally-administered anesthetics on these infants.

With respect to the first, very preterm neonates have the anatomy and functional, physiologic and chemical processes that they need in their brains responsible to mediate both pain and noxious stimuli. Anatomic studies have shown that the density of skin pain fibers are present in preterm and newborn infants and, in fact, may exceed the number of fibers of adult skin. These pain fibers begin around the mouth about the 7th week of gestation and are fully formed by 20 weeks of gestation.

Traditionally, lack of myelin, the coating around the nerve cell, has been used as an argument for stating why infants in this age group cannot feel pain. This has been proposed as an index of immaturity. However, we know that adults can perceive pain through nerves that are not myelinated, and more recent studies have shown that infants by 30 weeks of gestation have complete myelination up to and through the level of their brain.

Several types of scientific observation speak for the functional maturity of these infants' brains. The first is fetal and neonatal EEG patterns. Infants in this age group can respond both to visual and auditory stimulation. There are other brain waves that measure response to touch, pain, hot and cold, and these are documented in preterm infants up to—or beginning at 26 weeks gestation.

Also, there are well-defined periods of sleep and wakefulness present in utero, present from 28 weeks of gestation onward. Ultrasound findings have reported specific fetal movements in response to needle punctures in utero. Moreover, control studies of interuterine blood sampling and blood transfusions in fetuses between 20 and 34 weeks of gestation show that these infants release hormones that are consistent with perception of pain and were correlated with the duration of the painful stimulus.

Preterm infants who are born and delivered at 23 weeks of gestation show very highly specific and well-coordinated physiologic and behavioral responses to pain which is just like older infants.

My second point is there is increased sensitivity to pain in preterm infants. Contrary to previous teaching, current data now indicates that preterm neonates have greater pain sensitivity than term neonates or older infants. Several lines of scientific evidence support this, and I will review these briefly from the most basic to that which reflects my clinical practice.

First, in the study of pain reflexes, there are reflexes, one of which we call the cutaneous flexor response, which is a response that measures the connection between the distal pain fiber and the sensation in the brain. This is a well-described response and has been used to mark or parallel pain perception exactly.

Second, neurotransmitter substances cross from nerve to nerve, and these are present in high concentrations in these young infants.

Third, there are receptors for these transmitters in high density in the fetal brain.

Fourth, pain in the fetus and neonate can be measured by these hormones that I mentioned earlier. In studies of surgical procedures, these responses in preterm infants were three to five times those of adult patients undergoing similar types of surgery.

And, fifth, pain felt as a fetus or neonate can have a long-term health effect on the child's well being. Studies have shown that aggressive anesthesia is needed to decrease a stress response in preterm infants undergoing surgery, and, when done, improves their post-op clinical outcome.

Lastly, with respect to the effects of anesthesia on the fetus, as my colleagues have mentioned, local anesthetics rarely have any effect at all on the fetus. The mother's liver would clear these drugs as well as those given intravenously, and the concentration that reaches these babies does not achieve a therapeutic response. Mothers who underwent fetoscopy, their infants, when sampled for stress hormones, showed a much higher level when the mothers did not receive anesthesia. And these were infants of 16 to 20 weeks' gestation.

In conclusion, the scientific literature that I briefly reviewed and my own clinical practice has shown that the anatomic and functional processes that you need for the perception of pain are present in these infants who would be considered for partial-birth abortion. Second, these infants are more sensitive to pain than term infants or older children would be if they were having the same procedure. And, third, current methods of providing maternal anesthesia during partial-birth abortions is unlikely to prevent the experience of pain and stress in these preterm infants prior to their delivery.

Thank you. I'd be happy to entertain questions.

[The prepared statement of Dr. Wright follows:]

Prepared Statement of Jean A. Wright, M.D. Medical Director, Egleston Children's Hospital, Emory University

Chairman Canady, and members of the Subcommittee. My name is Jean A. Wright, MD., MBA. I am an Associate Professor of Pediatrics and Anesthesia at Emory University School of Medicine in Atlanta. I am also an Associate Professor at the Emory Center for Clinical Evaluation Sciences. I am board certified in Pediatrics, Anesthesia, and in both sub-boards of Critical Care Medicine. I have been a faculty member and a practicing physician since 1983.

I appreciate the invitation to testify before the Committee on the topic of the effects of anesthesia administered to a mother during a partial birth abortion. I understand that this committee was considering legislation which would ban "partial birth abortions," and that this is the second hearing on this topic. I will focus my testimony on the *ability of the fetus to feel and respond to pain during this procedure,* and on the effects of the anesthetic upon the fetus while administered to the mother.

My testimony will be divided into three parts. 1) The developmental aspects of pain in the fetus; 2) The increased sensitivity of preterm infants to pain compared to term or older infants; and 3) the effects of maternally administered anesthetics to blunt or alter the effect of this pain.

1. DEVELOPMENT OF THE PAIN SYSTEM IN THE HUMAN FETUS AND NEONATE

Very preterm neonates have the *neuroanatomic* substrate and functional physiologic and chemical processes in the brain responsible for mediating pain or noxious stimuli (known as nociception). [Fitzgerald and An and]. [See Chart from Anand & Hickey, NEJM, 1987]. *Anatomic* studies have shown that the density of the skin pain fibers (cutaneous nociceptive nerve endings) in the late fetus and newborn infant may equal or exceed that of adult skin. Early studies by Hooker showed that cutaneous sensory perception appears around the mouth of the human fetus in the *seventh week of gestation* and gradually spreads to all skin and mucous surfaces by 20 weeks.

Traditionally, lack of myelination (or the layer around the nerve fibers) has been proposed as an index of immaturity in the neonatal nervous system and used frequently to support the argument that neonates and infants are not capable of pain perception. However, pain (nociceptive) impulses in adults are conducted by unmyelinated or thinly myelinated fibers. Furthermore, Glues has shown that nerve tracts associated with pain in the spinal cord and brain stem are completely myelinated (up to the thalamus) by 30 weeks of gestation.

Several types of observations speak for the *functional maturity* of the brain (cerebral cortex) in the fetus and neonate. First are reports of *fetal and neonatal EEG patterns,* including cortical components of visual and auditory evoked potentials, that have been recorded in preterm babies of less than 28 weeks gestation. Cortical evoked potentials to somatosensory stimuli (touch, pain, heat, cold) were also recently documented in preterm neonates from 26 weeks gestation. Well defined periods of sleep and wakefulness are present in utero from 28 weeks gestation onward.

Ultrasonographic findings report *specific fetal movements in response to needle punctures in utero* (Robinson & Smotherman, 1992; Sival 1993). Moreover, a controlled study of intrauterine blood sampling and blood transfusions in fetuses between 20 and 34 weeks of gestation showed that hormonal responses that were consistent with fetal perception of pain, and were correlated with the duration of the painful stimulus (Giannakoulopuolos et al., 1994). Preterm neonates born at 23 weeks gestation show *highly specific and well coordinated physiologic and behavioral responses to pain,* similar to those seen in full-term neonates, older infants, and small children (summarized in "Pain in Neonates," Anand & McGrath, 1993).

2. INCREASED SENSITIVITY TO PAIN IN PRETERM INFANTS

Contrary to previous teaching, current data indicate that preterm neonates have greater pain sensitivity than term neonates or older age groups. Several lines of scientific evidence support this concept. I will review these from the most basic science, to that which reflects clinical practice.

1. Studies of reflex responses

The Cutaneous Flexor Reflex—has a lower threshold in preterm neonates than in term neonates or adults [Fitzgerald; Woolf]. The study of this reflex has been used to establish when connections between the skin and the spinal cord are first made in the fetus, and they have Been used to study the maturation of ascending motor pathways. This reflex has been shown in man to *parallel pain perception exactly* in terms of threshold, peak intensity, and sensitivity to analgesics.

2. Studies of neurotransmitting substances in the spinal cord

Neurotransmitter development in the dorsal horn of the spinal cord has demonstrated the early and abundant expression of the neurotransmitters mediating pain (e.g. substance P, L-glutamate, VIP, CGRP), and increased somatosensory excitability in the premature spinal cord. In contrast, the neurotransmitters contained in descending inhibitory fibers from supraspinal centers (5–HT, Norepi, Dopamine) were expressed postnatally, [Anand & Carr, 1989] implying *poorly developed gate control mechanisms for pain in preteen infants.*

3. Receptors for pain in the fetal brain

Opioid receptor labeling in the brain stem of fetuses 19–21 weeks gestation demonstrated very high densities in supraspinal centers associated with sensory perception [Kinney et al., 1990]. (These inhibitory Opioid receptors may protect developing neuronal systems from constant over stimulation, given the underdeveloped gate control mechanism in the dorsal horn of the spinal cord.)

4. Pain and stress are reflected in the hormones produced by the fetus

Pain in the fetus and neonate can be measured in two dimensions. Pain and surgical stress are demonstrated by a coordinated outpouring of pituitary, adrenal, and pancreatic hormones. Secondly, cardiovascular responses, such as increases in blood pressure, heart rate, dysrhythmias, or poor cardiac output may signal pain. The magnitude of hormonal (endocrine-metabolic) and other stress responses to invasive procedures or surgical operations was *much greater in neonates* as compared to adults; with neonatal catacholamine and metabolic responses up 3–5 times those of adult patients undergoing similar types of surgery [Anand].

5. Pain felt as a fetus or neonate has a long term effect on the child's well-being

The effects of anesthesia on the neonatal stress responses are important and may contribute to the effects of stress suppression on postoperative clinical outcome. In a randomized controlled trial, preterm babies undergoing ligation of the patient duct us arteriosus were given nitrous oxide and curare, with or without the addition of intravenous fentanyl. The hormonal responses of neonates receiving nitrous oxide alone were associated with significant increases in blood glucose, lactate, and pyruvate; these were prevented in neonates given therapeutic doses of fentanyl.

This study went on to show that *aggressive anesthesia not only decreased the stress responses of neonates undergoing surgery but also improved their postoperative clinical outcome.* Similarly, neonatal intensive care patients who are exposed to a single (circumcision) or repeated painful events (heelsticks) have been shown to have procedural memory for the event, and may have long term effects, even into adulthood.

6. The amount of medicine needed to achieve a desired effect

Pharmacokinetic studies of anesthetic drugs have shown *higher plasma concentrations were required to maintain effective surgical anesthesia in preterm neonates* as compared to old age groups [Yaster; Greeley & de Bruijn].

Developmental changes occur in the expression of pain which differentiate preterm from term or older infants; however, these findings illustrate a *communicational specificity and not changes in pain threshold during development* [Johnston]. The studies cited above indicate a lower pain threshold in preterm neonates, and the occurrence of further decreases in pain threshold following exposure to a painful stimulus or experience [Fitzgerald].

3. Effects of Anesthesia on the fetus

Obstetrical anesthesia has become a very safe practice, with many women a year receiving an anesthetic during the time of their pregnancy. These women are in addition to those who receive an anesthetic at the time of delivery. It is from this patient population that the effects of anesthesia on the fetus can be derived.

Local anesthetics rarely have any affect on the fetus. By their nature, their affect is to numb the nerves and tissues around the injection site, and only minuscule amounts of drug enter the mother's circulation, and even less reach the fetus.

The administration of intravenous sedation/anesthesia has minimal effects on the unborn due to two mechanisms: 1) The mother's liver clears much of the drug, and 2) the drug must cross from the mother's blood stream into the placenta before reaching the fetus.

Since the fetus has a much higher density of Opioid (pain) receptors, *scientific reasoning postulates that higher doses of Opioids will be required to saturate the increased number of receptors, and achieve a therapeutic response.*

Preliminary evidence for this therapeutic response is obtained from the decreased levels of steroid stress hormones in the amniotic fluid of fetuses whose mothers had received anesthesia as compared to the those that did not receive anesthesia in response to fetoscopy performed at 16–21 weeks gestation (Partsch et al., 1991). The mothers who had received anesthesia had a infant that was less stressed by the procedure.

CONCLUSIONS

The scientific literature reviewed above and my clinical experience in the delivery of general anesthesia, systemic analgesia, conscious sedation, local and regional anesthesia to a wide variety of patients lead me to believe that:

1. The anatomical and functional processes responsible for the perception of pain have developed in human fetuses that may be considered for "partial birth abortions." (At this stage of neurologic development, human fetuses respond to the pain caused by needle puncture in utero in a similar manner as older children or adults, within the limits of their behavioral repertoire).
2. It is likely that the *threshold for such pain perception is lower* than that of older preterm newborns, full-term newborns, and older age groups. Thus, the pain experienced during "partial birth abortions" by the human fetus would have *a much greater intensity than any similar procedures performed in older age groups.*
3. Current methods for providing maternal anesthesia during 'partial birth abortions' are unlikely to prevent the experience of pain and stress in the human fetuses before their death occurs after partial delivery.

SPECIAL ARTICLE

PAIN AND ITS EFFECTS IN THE HUMAN NEONATE AND FETUS

K.J.S. Anand, M.B.B.S., D.Phil., and P.R. Hickey, M.D.

THE evaluation of pain in the human fetus and neonate is difficult because pain is generally defined as a subjective phenomenon.[1] Early studies of neurologic development concluded that neonatal responses to painful stimuli were decorticate in nature and that perception or localization of pain was not present.[2] Furthermore, because neonates may not have memories of painful experiences, they were not thought capable of interpreting pain in a manner similar to that of adults.[3-5] On a theoretical basis, it was also argued that a high threshold of painful stimuli may be adaptive in protecting infants from pain during birth.[6] These traditional views have led to a widespread belief in the medical community that the human neonate or fetus may not be capable of perceiving pain.[7,8]

Strictly speaking, nociceptive activity, rather than pain, should be discussed with regard to the neonate, because pain is a sensation with strong emotional associations. The focus on pain perception in neonates and confusion over its differentiation from nociceptive activity and the accompanying physiologic responses have obscured the mounting evidence that nociception is important in the biology of the neonate. This is true regardless of any philosophical view on consciousness and "pain perception" in newborns. In the literature, terms relating to pain and nociception are used interchangeably; in this review, no further distinction between the two will generally be made.

One result of the pervasive view of neonatal pain is that newborns are frequently not given analgesic or anesthetic agents during invasive procedures, including surgery.[9-19] Despite recommendations to the contrary in textbooks on pediatric anesthesiology, the clinical practice of inducing minimal or no anesthesia in newborns, particularly if they are premature, is widespread.[9-19] Unfortunately, recommendations on neonatal anesthesia are made without reference to recent data about the development of perceptual mechanisms of pain and the physiologic responses to nociceptive activity in preterm and full-term neonates Even Robinson and Gregory's landmark paper demonstrating the safety of narcotic anesthesia in preterm neonates cites "philosophic objections" rather than any physiologic rationale as a basis for using this technique.[20] Although methodologic and other issues related to the study of pain in neonates have been discussed,[21-23] the body of scientific evidence regarding the mechanisms and effects of nociceptive

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activity in newborn infants has not been addressed directly.

Anatomical and Functional Requirements for Pain Perception

The neural pathways for pain may be traced from sensory receptors in the skin to sensory areas in the cerebral cortex of newborn infants. The density of nociceptive nerve endings in the skin of newborns is similar to or greater than that in adult skin.[24] Cutaneous sensory receptors appear in the perioral area of the human fetus in the 7th week of gestation; they spread to the rest of the face, the palms of the hands, and the soles of the feet by the 11th week, to the trunk and proximal parts of arms and legs by the 15th week, and to all cutaneous and mucous surfaces by the 20th week.[25,26] The spread of cutaneous receptors is preceded by the development of synapses between sensory fibers and interneurons in the dorsal horn of the spinal cord, which first appear during the sixth week of gestation.[27,28] Recent studies using electron microscopy and immunocytochemical methods show that the development of various types of cells in the dorsal horn (along with their laminar arrangement, synaptic interconnections, and specific neurotransmitter vesicles) begins before 13 to 14 weeks of gestation and is completed by 30 weeks.[29]

Lack of myelination has been proposed as an index of the lack of maturity in the neonatal nervous system[30] and is used frequently to support the argument that premature or full-term neonates are not capable of pain perception.[9-19] However, even in the peripheral nerves of adults, nociceptive impulses are carried through unmyelinated (C-polymodal) and thinly myelinated (A-delta) fibers.[31] Incomplete myelination merely implies a slower conduction velocity in the nerves or central nerve tracts of neonates, which is offset completely by the shorter interneuron and neuromuscular distances traveled by the impulse.[32] Moreover, quantitative neuroanatomical data have shown that nociceptive nerve tracts in the spinal cord and central nervous system undergo complete myelination during the second and third trimesters of gestation. Pain pathways to the brain stem and thalamus are completely myelinated by 30 weeks, whereas the thalamocortical pain fibers in the posterior limb of the internal capsule and corona radiata are myelinated by 37 weeks.[3]

Development of the fetal neocortex begins at 8 weeks of gestation, and by 20 weeks each cortex has a full complement of 10^9 neurons.[34] The dendritic processes of cortical neurons undergo profuse arborization and develop synaptic targets for the incoming thalamocortical fibers and intracortical connections.[35,36] The timing of the thalamocortical connection is of crucial importance for cortical perception, since most sensory pathways to the neocortex have synapses in the thalamus. Studies of primate and human fetuses have shown that afferent neurons in the thalamus produce axons that arrive in the cerebrum before mid-gestation. These fibers then "wait" just below the neocortex until migration and dendritic arborization of cortical neurons are complete and finally establish synaptic connections between 20 and 24 weeks of gestation (Fig. 1).[36-38]

Functional maturity of the cerebral cortex is suggested by fetal and neonatal electroencephalographic patterns, studies of cerebral metabolism, and the behavioral development of neonates. First, intermittent electroencephalographic bursts in both cerebral hemispheres are first seen at 20 weeks' gestation; they become sustained at 22 weeks and bilaterally synchronous at 26 to 27 weeks.[39] By 30 weeks, the distinction between wakefulness and sleep can be made on the basis of electroencephalographic patterns.[39,40] Cortical components of visual and auditory evoked potentials have been recorded in preterm babies (born earlier than 30 weeks of gestation),[40,41] whereas olfactory and tactile stimuli may also cause detectable changes in electroencephalograms of neonates.[40,42] Second, in vivo measurements of cerebral glucose utilization have shown that maximal metabolic activity is located in sensory

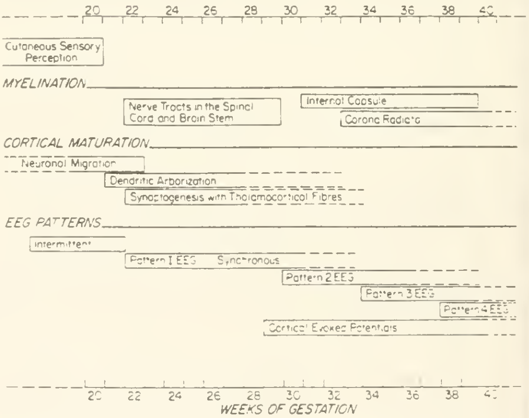

Figure 1. Schematic Diagram of the Development of Cutaneous Sensory Perception,[25] Myelination of the Pain Pathways,[32] Maturation of the Fetal Neocortex[33-37] and Electroencephalographic Patterns[38-40] in the Human Fetus and Neonate.

areas of the brain in neonates (the sensorimotor cortex, thalamus, and midbrain–brain-stem regions), further suggesting the functional maturity of these regions.[43] Third, several forms of behavior imply cortical function during fetal life. Well-defined periods of quiet sleep, active sleep, and wakefulness occur in utero beginning at 28 weeks of gestation.[44] In addition to the specific behavioral responses to pain described below, preterm and full-term babies have various cognitive, coordinative, and associative capabilities in response to visual and auditory stimuli, leaving no doubt about the presence of cortical function.[45]

Several lines of evidence suggest that the complete nervous system is active during prenatal development and that detrimental or developmental changes in any part would affect the entire system.[25,26,42,46] In studies in animals, Ralston found that somatosensory neurons of the neocortex respond to peripheral noxious stimuli and proposed that "it does not appear necessary to postulate a subcortical mechanism for appreciation of pain [in the fetus or neonate]."[47] Thus, human newborns do have the anatomical and functional components required for the perception of painful stimuli. Since these stimuli may undergo selective transmission, inhibition, or modulation by various neurotransmitters, the neurochemical mechanisms associated with pain pathways in the fetus and newborn are considered below.

Neurochemical Systems Associated with Pain Perception

The Tachykinin System

Various putative neurotransmitters called the tachykinins (substance P, neurokinin A, neuromedin K, and so forth) have been identified in the central nervous system, but only substance P has been investigated thoroughly and shown to have a role in the transmission and control of pain impulses.[48-56] Neural elements containing substance P and its receptors appear in the dorsal-root ganglia and dorsal horns of the spinal cord at 12 to 16 weeks of gestation.[57] A high density of substance P fibers and cells has been observed in multiple areas of the fetal brain stem associated with the pathways for pain perception and control and the visceral reactions to pain.[58-63] Substance P fibers and cells have also been found in the hypothalamus, mamillary bodies, thalamus, and cerebral cortex of human fetuses early in their development.[58] Many studies have found higher densities of substance P and its receptors in neonates than in adults of the same species, although the importance of this finding is unclear.[61,64-68]

The Endogenous Opioid System

With the demonstration of the existence of stereospecific opiate receptors[69,70] and their endogenous ligands,[71] the control of pain was suggested as a primary role for the endogenous opioid system.[illegible] Both the enkephalinergic and the endorphinergic systems may modulate pain transmission at spinal and supraspinal levels.[56,73] In the human fetus, however, there are few data on the ontogeny and distribution of specific cells, fibers, and receptors (mu-, delta-, and kappa-opiate receptors) that are thought to mediate the antinociceptive effects of exogenous and endogenous opioids.[illegible] However, functionally mature endorphinergic cells in fetal pituitary glands have been observed at 15 weeks of gestation and possibly earlier.[illegible] Beta-endorphin and beta-lipotropin were found to be secreted from fetal pituitary cells at 20 weeks in response to in vitro stimulation by corticotropin-releasing factor.[illegible] In addition, more production of beta-endorphin may occur in fetal and neonatal pituitary glands than in adult glands.[78,79]

Endogenous opioids are released in the human fetus at birth and in response to fetal and neonatal distress.[80] Umbilical-cord plasma levels of beta-endorphin and beta-lipotropin from healthy full-term neonates delivered vaginally or by cesarean section have been shown to be three to five times higher than plasma levels in resting adults.[78,81] Neonates delivered vaginally by breech presentation or vacuum extraction had further increases in beta-endorphin levels, indicating beta-endorphin secretion in response to stress at birth.[82] Plasma beta-endorphin concentrations correlated negatively with umbilical-artery pH and partial pressure of oxygen and positively with base deficit and partial pressure of carbon dioxide, suggesting that birth asphyxia may be a potent stimulus to the release of endogenous opioids.[80,83-87] Cerebrospinal fluid levels of beta-endorphin were also increased markedly in newborns with apnea of prematurity,[88-90] infections, or hypoxemia.[83,91,92] These elevated values may have been caused by the "stress" of illness,[93] the pain associated with these clinical conditions, or the invasive procedures required for their treatment. However, these high levels of beta-endorphin are unlikely to decrease anesthetic or analgesic requirements,[94] because the cerebrospinal fluid levels of beta-endorphin required to produce analgesia in human adults have been found to be 10,000 times higher than the highest recorded levels in neonates.[95]

The high levels of beta-endorphin and beta-lipotropin in cord plasma decreased substantially by 24 hours after birth[87,96] and reached adult levels by five days, whereas the levels in the cerebrospinal fluid fell to adult values in 24 hours.[87,97,98] In newborn infants of women addicted to narcotics, massive increases in plasma concentrations of beta-endorphin, beta-lipotropin, and metenkephalin occurred within 24 hours, with some values reaching 1000 times those in resting adults. Markedly increased levels persisted for up to 40 days after birth.[87] However, these neonates were considered to be clinically normal, and no behavioral effects were observed (probably because of the development of prenatal opiate tolerance).

PHYSIOLOGIC CHANGES ASSOCIATED WITH PAIN

Cardiorespiratory Changes

Changes in cardiovascular variables, transcutaneous partial pressure of oxygen, and palmar sweating have been observed in neonates undergoing painful clinical procedures. In preterm and full-term neonates undergoing circumcision[99,100] or heel lancing,[101-103] marked increases in the heart rate and blood pressure occurred during and after the procedure. The magnitude of changes in the heart rate was related to the intensity and duration of the stimulus[104] and to the individual temperaments of the babies.[105] The administration of local anesthesia to full-term neonates undergoing circumcision prevented the changes in heart rate and blood pressure,[99,100,106] whereas giving a "pacifier" to preterm neonates during heel-stick procedures did not alter their cardiovascular or respiratory responses to pain.[101] Further studies in newborn and older infants showed that noxious stimuli were associated with an increase in heart rate, whereas non-noxious stimuli (which elicited the attention or orientation of infants) caused a decrease in heart rate.[22,107,108]

Large fluctuations in transcutaneous partial pressure of oxygen above and below an arbitrary "safe" range of 50 to 100 mm Hg have been observed during various surgical procedures in neonates.[109-111] Marked decreases in transcutaneous partial pressure of oxygen also occurred during circumcision,[106,112] but such changes were prevented in neonates given local analgesic agents.[100,106,112] Tracheal intubation in awake preterm and full-term neonates caused a significant decrease in transcutaneous partial pressure of oxygen, together with increases in arterial blood pressure[113-115] and intracranial pressure.[116] The increases in intracranial pressure with intubation were abolished in preterm neonates who were anesthetized.[117] In addition, infants' cardiovascular responses to tracheal suctioning were abolished by opiate-induced analgesia.[118]

Palmar sweating has also been validated as a physiologic measure of the emotional state in full-term babies and has been closely related to their state of arousal and crying activity.[119] Substantial changes in palmar sweating were observed in neonates undergoing heel-sticks for blood sampling, and subsequently a mechanical method of heel lancing proved to be less painful than manual methods, on the basis of the amount of palmar sweating.[120]

Hormonal and Metabolic Changes

Hormonal and metabolic changes have been measured primarily in neonates undergoing surgery, although there are limited data on the neonatal responses to venipuncture and other minor procedures. Plasma renin activity increased significantly 5 minutes after venipuncture in full-term neonates and returned to basal levels 60 minutes thereafter; no changes occurred in the plasma levels of cortisol, epinephrine, or norepinephrine after venipuncture.[121] In preterm neonates receiving ventilation therapy, chest physiotherapy and endotracheal suctioning produced significant increases in plasma epinephrine and norepinephrine; this response was decreased in sedated infants.[122] In neonates undergoing circumcision without anesthesia, plasma cortisol levels increased markedly during and after the procedure.[123,124] Similar changes in cortisol levels were not inhibited in a small number of neonates given a local anesthetic,[125] but the efficacy of the nerve block was questionable in these cases.

Further detailed hormonal studies[126] in preterm and full-term neonates who underwent surgery under minimal anesthesia documented a marked release of catecholamines,[127] growth hormone,[128] glucagon,[129] cortisol, aldosterone, and other corticosteroids,[130] as well as suppression of insulin secretion.[131] These responses resulted in the breakdown of carbohydrate and fat stores,[127,132,133] leading to severe and prolonged hyperglycemia and marked increases in blood lactate, pyruvate, total ketone bodies, and nonesterified fatty acids. Increased protein breakdown was documented during and after surgery by changes in plasma amino acids, elevated nitrogen excretion, and increased 3-methylhistidine:creatinine ratios in the urine (Anand KJS, Aynsley-Green A: unpublished data). Marked differences also occurred between the stress responses of premature and full-term neonates (Anand KJS, Aynsley-Green A: unpublished data) and between the responses of neonates undergoing different degrees of surgical stress.[134]

Possibly because of the lack of deep anesthesia, neonatal stress responses were found to be three to five times greater than those in adults, although the duration was shorter.[126] These stress responses could be inhibited by potent anesthetics, as demonstrated by randomized, controlled trials of halothane and fentanyl. These trials showed that endocrine and metabolic stress responses were decreased by halothane anesthesia in full-term neonates[135] and abolished by low-dose fentanyl anesthesia in preterm neonates.[136] The stress responses of neonates undergoing cardiac surgery were also decreased in randomized trials of high-dose fentanyl and sufentanil anesthesia.[126,137,138] These results indicated that the nociceptive stimuli during surgery performed with minimal anesthesia were responsible for the massive stress responses of neonates. Neonates who were given potent anesthetics in these randomized trials were more clinically stable during surgery and had fewer postoperative complications as compared with neonates under minimal anesthesia.[127,128] There is preliminary evidence that the pathologic stress responses of neonates under light anesthesia during major cardiac surgery may be associated with an increased postoperative morbidity and mortality (Anand KJS, Hickey PR: unpublished data). Changes in plasma stress hormones (e.g., cortisol) can also be correlated with the behavioral states of newborn infants,[124,139,140] which are important in the postulation of overt subjective distress in neonates responding to pain.

Behavioral Changes Associated with Pain

Simple Motor Responses

Early studies of the motor responses of newborn infants to pinpricks reported that the babies responded with a "diffuse body movement" rather than a purposeful withdrawal of the limb,[2] whereas other studies found reflex withdrawal to be the most common response.[141-143] More recently, the motor responses of 124 healthy full-term neonates to a pinprick in the leg were reported to be flexion and adduction of the upper and lower limbs associated with grimacing, crying, or both, and these responses were subsequently quantified.[144,145] Similar responses have also been documented in very premature neonates, and in a recent study, Fitzgerald et al. found that premature neonates (<30 weeks) not only had lower thresholds for a flexor response but also had increased sensitization after repeated stimulation.[146]

Facial Expressions

Distinct facial expressions are associated with pleasure, pain, sadness, and surprise in infants.[147] These expressions, especially those associated with pain, have been objectively classified and validated in a study of infants being immunized.[102,148] With use of another method of objectively classifying facial expressions of neonates, different responses were observed with different techniques of heel lancing and with different behavioral states[149] (and Grunau RVE, Craig KD: unpublished data). These findings suggest that the neonatal response to pain is complex and may be altered by the behavioral state and other factors at the time of the stimulus.[150]

Crying

Crying is the primary method of communication in newborn infants and is also elicited by stimuli other than pain.[151] Several studies have classified infant crying according to the type of distress indicated and its spectrographic properties.[152-154] These studies have shown that cries due to pain, hunger, or fear can be distinguished reliably by the subjective evaluation of trained observers and by spectrographic analysis.[155-160] This has allowed the cry response to be used as a measure of pain in numerous recent studies.[22,99,100,102,106,152]

The pain cry has specific behavioral characteristics and spectrographic properties in healthy full-term neonates.[161-164] Pain cries of preterm neonates and neonates with neurologic impairment, hyperbilirubinemia, or meningitis are considerably different, thereby indicating altered cortical function in these babies.[165-168] Changes in the patterns of neonatal cries have been correlated with the intensity of pain experienced during circumcision and were accurately differentiated by adult listeners.[169] In other studies of the cry response to painful procedures, neonates were found to be more sensitive to pain than older infants (those 3 to 12 months old) but had similar latency periods between exposure to a painful stimulus and crying or another motor response.[illegible] This supports the contention that slower conduction speed in the nerves of neonates is offset by the smaller interneuron distances traveled by the impulse.

Complex Behavioral Responses

Alterations in complex behavior and sleep–wake cycles have been studied mainly in newborn infants undergoing circumcision without anesthesia. Emde and coworkers observed that painful procedures were followed by prolonged periods of non-rapid-eye-movement sleep in newborns and confirmed these observations in a controlled study of neonates undergoing circumcision without anesthesia.[illegible] Similar observations have been made in adults with prolonged stress. Other subsequent studies have found increased wakefulness and irritability for an hour after circumcision, an altered arousal level in circumcised male infants as compared with female and uncircumcised male infants, and an altered sleep–wake state in neonates undergoing heel-stick procedures.[165,172,173] In a double-blind, randomized controlled study using the Brazelton Neonatal Behavioral Assessment Scale, 90 percent of neonates had changed behavioral states for more than 22 hours after circumcision, whereas only 46 percent of the uncircumcised infants did.[174] It was therefore proposed that such painful procedures may have prolonged effects on the neurologic and psychosocial development of neonates.[175] A similar randomized study showed the absence of these behavioral changes in neonates given local anesthetics for circumcision.[176] For two days after circumcision, neonates who had received anesthetics were more attentive to various stimuli and had greater orientation, better motor responses, decreased irritability, and a greater ability to quiet themselves when disturbed. A recent controlled study showed that intervention designed to decrease the amount of sensory input and the intensity of stressful stimuli during intensive care of preterm neonates was associated with improved clinical and developmental outcomes.[177] Because of their social validity and communicational specificity, the behavioral responses observed suggest that the neonatal response to pain is not just a reflex response.[178-18]

Memory of Pain in Neonates

The persistence of specific behavioral changes after circumcision in neonates implies the presence of memory. In the short term, these behavioral changes may disrupt the adaptation of newborn infants to their postnatal environment,[174-176] the development of parent–infant bonding, and feeding schedules.[illegible] In the long term, painful experiences in neonates could possibly lead to psychological sequelae,[illegible] since several workers have shown that newborns may have a much greater capacity for memory than was previously thought.[183-186]

Pain itself cannot be remembered, even by adults[187]; only the experiences associated with pain can be recalled. However, the question of memory is important, since it has been argued that memory traces are necessary for the "maturation" of pain perception,[5] and a painful experience may not be deemed important if it is not remembered. Long-term memory requires the functional integrity of the limbic system and diencephalon (specifically, the hippocampus, amygdala, anterior and mediodorsal thalamic nuclei, and mamillary nuclei)[188]; these structures are well developed and functioning during the newborn period.[4-] Furthermore, the cellular, synaptic, and molecular changes required for memory and learning depend on brain plasticity, which is known to be highest during the late prenatal and neonatal periods.[189,190] Apart from excellent studies in animals demonstrating the long-term effects of sensory experiences in the neonatal period,[191] evidence for memories of pain in human infants must, by necessity, be anecdotal.[178,192,193] Early painful experiences may be stored in the phylogenically old "procedural memory," which is not accessible to conscious recall.[182,183,194] Although Janov[195] and Holden[196] have collected clinical data that they claim indicate that adult neuroses or psychosomatic illnesses may have their origins in painful memories acquired during infancy or even neonatal life, their findings have not been substantiated or widely accepted by other workers.

Conclusions

Numerous lines of evidence suggest that even in the human fetus, pain pathways as well as cortical and subcortical centers necessary for pain perception are well developed late in gestation, and the neurochemical systems now known to be associated with pain transmission and modulation are intact and functional. Physiologic responses to painful stimuli have been well documented in neonates of various gestational ages and are reflected in hormonal, metabolic, and cardiorespiratory changes similar to but greater than those observed in adult subjects. Other responses in newborn infants are suggestive of integrated emotional and behavioral responses to pain and are retained in memory long enough to modify subsequent behavior patterns.

None of the data cited herein tell us whether neonatal nociceptive activity and associated responses are experienced subjectively by the neonate as pain similar to that experienced by older children and adults. However, the evidence does show that marked nociceptive activity clearly constitutes a physiologic and perhaps even a psychological form of stress in premature or full-term neonates. Attenuation of the deleterious effects of pathologic neonatal stress responses by the use of various anesthetic techniques has now been demonstrated. Recent editorials addressing these issues have promulgated a wide range of opinions, without reviewing all the available evidence.[197-201] The evidence summarized in this paper provides a physiologic rationale for evaluating the risks of sedation, analgesia, local anesthesia, or general anesthesia during invasive procedures in neonates and young infants. Like persons caring for patients of other ages, those caring for neonates must evaluate the risks and benefits of using analgesic and anesthetic techniques in individual patients. However, in decisions about the use of these techniques, current knowledge suggests that humane considerations should apply as forcefully to the care of neonates and young, nonverbal infants as they do to children and adults in similar painful and stressful situations.

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Letters to the Editor

HYPERALGESIA IN PREMATURE INFANTS

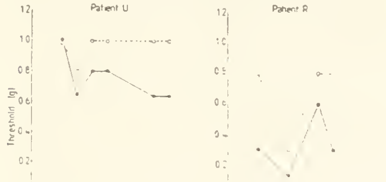
SIR,—Pain in the newborn infant is an important issue but it is difficult to measure pain in babies and to assess pain control. Even more fundamental is the question of whether the immature nervous system can analyse and respond to noxious inputs in an organised way.

We have used the flexor reflex threshold as a measure of sensation in the newborn premature infant. This spinal reflex is a useful measure of nociceptive function in the central nervous system.[1] The threshold of the flexor reflex parallels perceived pain in adults, as does its susceptibility to analgesics such as morphine.[2,3] In the rat cutaneous inputs to the spinal cord that activate flexor reflex motoneurones also activate nociceptive projection pathways to the brain.[4] Local tissue injury and inflammation produce a drop in the threshold that mimics the tenderness or hyperalgesia perceived at higher levels of the central nervous system.[5]

Newborn full-term and premature infants show a well-developed flexion withdrawal reflex with a clearly defined threshold when measured with graded mechanical stimulation of the sole of the foot.[6] The intensity of cutaneous stimulation required to evoke the reflex is lower than in adults but increases with postconceptional age.[6] We have compared the threshold of the flexor reflex in infants when evoked from an area of normal and of damaged skin. We wanted to find out if the drop in reflex threshold that accompanies tenderness and hyperalgesia in adults also happens in newborn premature infants.

The study was done on eleven babies born at 26–32 weeks. None had intracerebral haemorrhage or unduly high oxygen requirements and the final outcome was excellent. Heel lancing, used routinely to collect blood samples in the special baby care unit, was confined to the lateral side of one heel. Repeated lancing produces localised tissue damage, but samples were taken only when clinically indicated. Flexor reflex thresholds were tested daily (if possible) for 2–14 days, with the infants awake or in a light sleep. Thresholds were measured on both heels using calibrated von Frey hairs.[6] The hairs were applied to the area of tissue damage and to the exactly equivalent position on the uninjured contralateral side.

In all cases, the threshold on the injured (lanced) heel was lower than it was on the control side. The threshold on the control side averaged 1·99 (SEM 0·3) g for 36 tests on eleven babies, agreeing well with previous findings,[6] while on the injured side the threshold was significantly lower (1·05 [0·2] g). Where testing began 1–4 weeks after birth when routine lancing was well established (six babies) the lower threshold on the damaged heel was clear from the beginning (figure, b). Where tests began soon after birth (five babies), the difference did not emerge for 1–2 days, when the heel had been lanced several times (figure, a). The figure illustrates the natural variation in threshold that occurs over the period of testing, but the threshold was consistently lower on the damaged heel.



Flexor reflex thresholds on lateral sole of foot in two premature infants.

○ - - - - ○ = control (intact), ● —— ● = repeatedly lanced foot (local tissue injury). Patient U tested from day after birth at 30 weeks, patient R tested from 2 weeks after birth at 27 weeks. Despite fluctuating daily readings both infants have consistently lower thresholds on injured side.

Thus premature infants can indeed show a well-defined hypersensitivity to injury analogous to that observed in adults. In adults such post-injury hypersensitivity in the flexor reflex parallels post-injury hyperalgesia. The aim now is to use this hypersensitivity to assess the efficacy of analgesics in premature babies. Despite an infant's lack of ability to report pain, neural mechanisms capable of reacting to tissue injury are clearly present.

This work was supported by the Medical Research Council and by a Nuffield Foundation vacation award to C. M.

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PLOIDY AS PROGNOSTIC DETERMINANT IN LUNG CANCER

SIR,—The use of the terms diploid and aneuploid by Dr Pujol and colleagues (Nov 28, p 1276) illustrates the confusion that may result when they are applied to quantitative DNA estimations and not chromosomal analyses. As Koss[1] has pointed out, the term diploid is not applicable to human cancer because few, if any, solid tumours have a chromosomal complement that is normal in number and configuration, and hence are truly diploid. An appropriate term for tumours whose DNA contents are close to or within normal limits is "tumours in the diploid range". Unfortunately studies describing tumours as diploid or aneuploid on the basis of DNA measurements continue to appear despite the recommendation a few years ago that this use of the terms be discontinued (although "DNA aneuploidy" might be acceptable as a synonym for abnormal DNA stemline).[2]

On the basis of our experience and that of others we would dispute Pujol and colleagues' statement that "some highly malignant tumours are strictly diploid", at least as far as human cancer is concerned.

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UPDATED KIEL CLASSIFICATION FOR LYMPHOMAS

SIR,—Much progress has been made in our understanding of the malignant lymphomas since we wrote to *The Lancet* in 1974[1] proposing the classification which has since become widely known as the Kiel classification. As members of the European Lymphoma Club (including four signatories of the original *Lancet* letter), we feel that the time is now ripe for an updating of the Kiel classification, incorporating information derived from newer immunological and molecular biological techniques. Useful as such techniques have proved in elucidating the B or T lineage of lymphoid cells and in revealing their activation status and degree of proliferative activity, the basis of lymphoma classification must remain morphological, at least in the foreseeable future.

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Can a fetus feel pain?

Is a fetus capable of experiencing pain? This question is one of increasing concern, and not merely to neonatologists and experts on embryonic development. Thus a meeting billed "Pain and the Fetus," organised by the Ciba Foundation might have appealed to a wide audience. In the event it was a ect affair open to only two dozen invited experts from ecialties including paediatrics, pathology, neurochemical pharmacology, and child psychology.

Much of the data that were presented were based on research carried out in animals and preliminary unpublished studies, so not surprisingly conclusions were guarded—even to the extent that by mid-afternoon the chairman, Professor P D Wall, an anatomist from University College London, was not prepared to say more than that the answer to the question does the fetus or premature baby feel pain was not "no" but "Who knows?" For those who would regard this as an unsatisfactory, if accurate, scientific observation the clinicians produced more tangible information.

"It is likely," said Dr C H Rodeck, an obstetrician from King's College, London, "that the fetus responds to some forms of sensory stimulation, particularly noise, changes in position, and pain." Invasive procedures such as amniocentesis and chorionic villous sampling may well have adverse effects—amniocentesis was known to be associated with an increased incidence of pulmonary hyperplasia, but it was too early to say if it results in damage to the central nervous system.

Further evidence to suggest that the neonate—if not the fetus—responds to noxious stimuli came from Dr M L Chiswick, a consultant paediatrician from Manchester, who reported the results of a study of basal skin conductance in neonates. (Changes in skin conductance are known to be a measure of the response to stress and are the basis of the "lie ector.") Conductance was significantly increased in abies who had undergone vaginal delivery compared with those who had been delivered by caesarean section. This and further studies led him to suggest that the longer and more baby. (Whether this was [illegible]

A similar increase in conductance was also see ately after an infant was subjected to a heel stab to o blood sample. This plus simple observation of infa special care baby units convinced him that infan experience pain and distress even though their res were obviously limited.

"Mention of inflicting pain on neonates introduced was unquestionably the most clinically relevant topic o day. Dr K J S Anand, a research fellow from the Radcliffe Hospital, Oxford, showed that babies who un major surgery show large increases in a variety of di metabolic and hormonal variables. Furthermore, t infants who have surgery carried out under minimal a thesia show much greater rises than those who are g potent anaesthesia."

Clearly it came as a surprise to some of the audience t that some surgery and certain invasive procedures in nates are carried out with only minimal anaesthe analgesia in some hospitals in Britain, Europe, and Am This is done on the assumption that because preterm even term infants have no memory of pain they are pr not capable of discriminating painful from other stimuli because anaesthetic agents may have adverse effects o cardiovascular and respiratory systems they are best a Dr Anand said that as a result of his work the p anaesthetists in Oxford have changed their practice and ensure that the babies have fully adequate anaesthesia analgesia. They also now give more postoperative analg One or two members of the audience voiced their con that this stress at or soon after birth may have long psychological sequelae.

There seems no doubt that the neonate and possibly fetus is capable of "feeling" considerably more than is u appreciated. It is to be hoped that Dr Chiswick's sugges that those who work in special care baby units sh get together and review their policies on management promptly taken up.

TESSA RIC

Assistant Editor,
BMJ

National Health Service: control of nursing manpower

Whether or not the National Health Service is "safe in hands," a government committed to a reduction in pu expenditure might be expected to look critically at nur manpower. In the year 1983-4 nurses' salaries cost £3 million, accounting for 34% of the NHS budget—and ne 3% of all public expenditure.[1] Nursing manpower this context includes all grades of qualified staff, lea (pupil and student nurses), and unqualified staff (nur auxiliaries). Nursing auxiliaries are quite properly inclu in the nursing budget, but it is unfortunate that yet ano government document classifies them as "nurses." Not does this put a group with little or (in most cases) no trai on the same level as those who have undergone training b also leads the public to think that they, and their relatives, being cared for by qualified staff.

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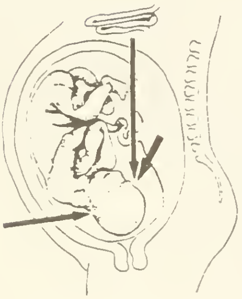
WHAT THE FETUS FEELS

Sound



The fetus's environment is disturbed by sound, light and touch, and he responds to these disturbances by moving.

Until the late nineteenth century babies were thought to be deaf as well as dumb. In fact the inner ear of the fetus is completely developed by mid-pregnancy, and the fetus responds to a wide variety of sound.

He is surrounded by a constant very loud noise in the uterus—the rhythmical sound of the uterine blood supply punctuated by the noises of air passing through the mother's intestine. Loud noises from outside the uterus such as the slamming of a door or loud music reach the fetus and he reacts to them. The fetus also responds to sounds in frequencies so high or low that they cannot be heard by the human adult ear, which suggests that sensory pathways other than the ear are implicated. Movements of the fetus tend to be inhibited by low frequencies and increased by high frequencies.

Doppler ultrasound used for monitoring fetal heart rate appears to provoke fetal activity. Ultrasound used for imaging does not affect the fetus.

After birth a mother tends to hold her baby on the left breast. There the infant can hear his mother's heartbeat, which provides the same type of rhythm that was present in the uterus and which appears to have a calming effect. Recordings of the adult heartbeat or of the noise in the uterus have a calming effect on infants when they are played to them.

Vision

Muscles within the orbit are present very early in pregnancy, and the fetus's eyes move when he changes position and during sleep. In late pregnancy some light penetrates through the uterine wall and amniotic fluid, and fetal activity has been shown to increase in response to bright light.

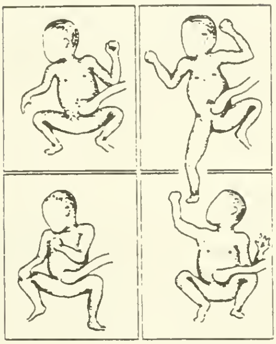
In preterm infants changes in the electroencephalogram occur in response to light, and the repeated flashing of a light will quieten babies.

The fetus can touch parts of his body with his hands and the umbilical cord also touches all parts of his body. But in the early stages he tends to move away from objects he touches; later he moves towards them.

Nine weeks after conception the baby is well enough formed that he can bend his fingers round an object in the palm of his hand. In response to a touch on the sole of his foot he will curl his toes or bend his hips and knees to move away from the touching object. At 12 weeks he can close his fingers and thumb and he will open his mouth in response to pressure applied at the base of the thumb.

At first when his hands touch his mouth the fetus turns his head away, though his mouth opens. Later the fetus may turn his head towards his hand and even put a finger into his open mouth and suck it. This reflex—the rooting reflex—persists after birth. Then it is usually the mother's nipple that touches the baby in this way.

Spontaneous movements



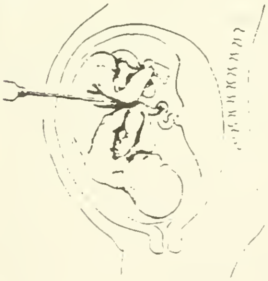
Although the fetus starts making spontaneous movements at about 7½ weeks after conception, mothers do not usually feel their babies moving until about 16 to 21 weeks. The types of movements the fetus makes include slow squirmy movements, sharp kicks, and small rhythmic kicks. The squirming tends to increase during pregnancy, while the rhythmic kicks continue at a constant rate from the fifth to the ninth month. The sharp kicks increase up to the seventh month and then diminish.

Some of these movements show a cyclical pattern, which might be related to the fetus's sleep pattern. Later in pregnancy the fetus tends to sleep at the same time as his mother.

The fetus's level of activity increases when the mother is under emotional stress. If the stress is prolonged there is a corresponding increase in the fetus's movements—up to 10 times their normal level. The fetus's activity also seems to be increased when the mother is tired.

At 11 weeks after conception the fetus starts to swallow the surrounding amniotic fluid and to pass it back as his urine. He can also produce complex facial expressions and even smile. Towards the end of pregnancy the fetus's chest wall expands and contracts, as if he were breathing. These movements, which occur about 70% of the time, are often interrupted by sighs and hiccups. A decrease in fetal chest and limb movements occurs a few days before fetal death.

Pain



The fetus needs to be heavily sedated by sedating the mother before intrauterine manipulations such as transfusions. Otherwise he will move away from the needle, which cannot then be inserted into the peritoneal cavity. Fetal heart rate and movement increase for a few minutes after tactile stimuli during amniocentesis. The fetus settles down again within a few minutes of the procedure's ending.

The changes in heart rate and increase in movement suggest that these stimuli are painful for the fetus. Certainly it cannot be comfortable for the fetus to have a scalp electrode implanted on his skin, to have blood taken from the scalp, or to suffer the skull compression that may occur even with spontaneous delivery. It is hardly surprising that infants delivered by difficult forceps extraction act as if they have a severe headache.

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Acute Pain in Children 0031–3955/89 $0.00 + .20

The Neuroanatomy, Neurophysiology, and Neurochemistry of Pain, Stress, and Analgesia in Newborns and Children

K. J. S. Anand, MBBS, D Phil, and D. B. Carr, MD†*

In recent years, broad similarities between the experience of pain in children and adults have become increasingly evident. Although recognition of these parallels carries great weight for clinical practice, for example, in mandating aggressive analgesia for the young, essential differences exist between the pain experienced by children and adults. These differences reflect the unique biologic and behavioral characteristics of newborns, infants, and children in different stages of development. Craig and colleagues[45] have stated that "the challenge for adults is to understand just what it is that children are experiencing. Adults do not think and feel like children." This volume is evidence for evolving concern for pain issues in pediatric patients, and its contents are testimony to the numerous scientific advances and changes in clinical practice presently occurring in this field.

Another article in this issue describes the cultural indifference with which pain in newborns and children has been treated until the recent past. Clinicians long have been misguided by the premise that neonatal and pediatric patients do not experience pain as severely as adults, and that the magnitude and duration of its impact may be less than in adults. This article presents the scientific foundations for the physiology of pain as expressed in the pediatric age group, its clinical correlates, and implications for clinical outcome. The present discussion therefore may provide a physiologic rationale for the treatment of pain described in subsequent articles.

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NEUROANATOMY AND PHYSIOLOGY

Pain: A Dynamic Process in the Central Nervous System

Pain has been depicted as a process in which the activation of specific receptors in the periphery evokes reproducible responses within spinal cord dorsal horn neurons that in turn send projections to well-demarcated cephalad loci.[91] This "hard-wired" model, along with other straightforward categorizations of pain mechanisms, has been abandoned by researchers in this field because overwhelming evidence has accumulated that the phenomenon of pain reflects remarkably adaptive neural and chemical processes within networks, the elements of which may grow or dwindle in number.[175]

Wall recently has critiqued traditional classifications of nociceptive neurons.[178] Based on the absence of fixed relationships between excitation of peripheral fibers and sensory or behavioral outcome, or between input and output of individual dorsal horn neurons, Wall argues persuasively that input–output schemes within pain pathways are context dependent. For example, painful inputs trigger widespread increases of neural excitability within the spinal cord, and expansion of these spinal neurons' cutaneous receptive fields.[45, 179, 191] The description of constantly shifting patterns of interneuronal communication within pain pathways recalls Sperry's seminal picture of consciousness itself[161] and is a far cry from "the classical expectation of hard-wired dedicated systems monopolized in the service of a single sensation."[175] Nonetheless, certain areas of the nervous system are recognized to be particularly dense foci of processing and modulation of nociceptive inputs[187, 194]; these are summarized in Figure 1. Within each level, convergence and summation of incoming signals occurs in multiple time frames through both excitatory and inhibitory afferent projections. Excitatory and inhibitory descending projections to spinal and supraspinal loci are interwoven with ascending circuits to produce exquisitely variable filtering or enhancement of potentially painful afferent stimuli.

Mature Anatomic Pathways: A Précis

Acute pain relevant to the hospitalized child typically reflects the activation of nociceptors.[28, 187, 194] In broad terms, these are of two major types: high-threshold mechanoceptors and polymodal nociceptors. The former do not respond to heat or chemical irritation but do respond to strong pressure applied to a wide area of skin. Axons of high-threshold mechanoceptors are myelinated and conduct in the A-delta velocity range, 5 to 25 meters per second. Polymodal nociceptors respond to heat and algesic substances as well as to pressure. Being unmyelinated, the axons of polymodal nociceptors conduct slowly, in the C-fiber range (less than 2 meters per second). Nociceptors project to the spinal cord through primary afferents with cell bodies in dorsal root ganglia and increase in sensitivity after injury.

Classically, selective stimulation of fast, myelinated A-delta fibers yields *first pain:* rapid in onset after injury, sharp, localized, and pricking. *Second pain*—slower in onset, prolonged, dull, aching, and poorly localized—is identified with C-fiber effects. Visceral afferents may be of A- or C-caliber

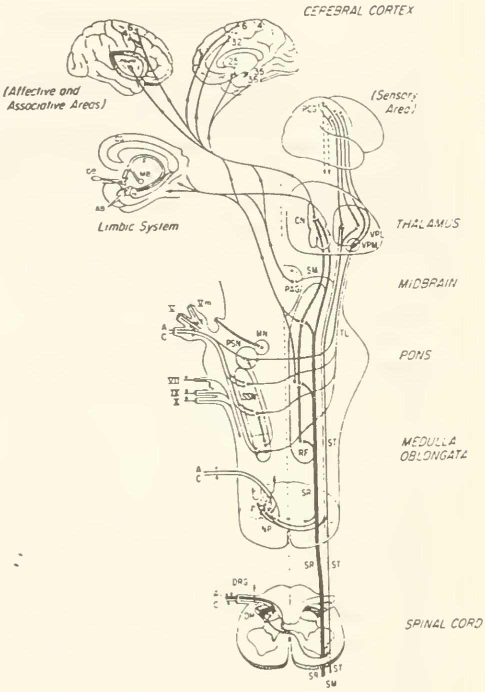

Figure 1. Pain pathways from the spinal cord to the sensory cortex, including connections to affective and associative areas. (Abbreviations follow standard neuroanatomical nomenclature.)

but, in contrast to somatic afferents, reach the spinal cord through sympathetic, parasympathetic, and splanchnic nerves.

Upon reaching the spinal cord, afferent nociceptive signals are amplified or attenuated within the layers of the dorsal horn. Nociceptive-specific (NS) neurons within the substantial gelatinosa of the superficial dorsal horn respond only to pain. Wide dynamic range (WDR) neurons, particularly in deeper layers, respond to various input modes (e.g., mechanical, thermal, or chemical) even at a low, non-noxious intensity. Multiple incoming and descending stimuli combine to modulate the discharge patterns of dorsal horn cells. Woolf has shown that under conditions of stimulation, such as produced by peripheral tissue injury, the threshold of NS neurons is considerably lowered, thereby converting them to WDR neurons.[181, 159] This hypersensitivity, associated with alteration in the receptive fields of such neurons, is exquisitely sensitive to treatment with opioid analgesics.[180]

Such nociceptive discharges are conveyed via axons that largely cross to ascend in the contralateral spinal cord. The spinothalamic tract, in the anterolateral cord, ascends to ventroposterior and medial thalamic nuclei and thence to associative and somatosensory areas of cerebral cortex that mediate the discriminative and localizing aspects of pain. Spinoreticular neurons project to the limbic system (including hypothalamus), and mediate arousal, affective responses, and neuroendocrine and autonomic sequelae of nociceptive input. Pain sensations may persist or recur even after sectioning of both these ascending tracts owing to persistence of spinomesencephalic projections.

Development of the Anatomic Substrate for Pain

The development of anatomic substrates required for pain transmission occurs mainly during fetal life and in the first months of infancy. The gross elements of the pain system may be traced from sensory receptors in the skin to the sensory cerebral cortex: this linked array serves as a framework for describing the development and integration of its components. Anatomic studies have shown that the density of cutaneous nociceptive nerve endings in the late fetus and newborn infant may equal or exceed that of adult skin.[73] Recent recordings from single cutaneous afferents in newborn and fetal rats also have shown that the receptive field sizes are similar to those in the adult.[55] Early studies by Hooker and his colleagues showed that cutaneous sensory perception appears in the perioral area of the human fetus in the seventh week of gestation and gradually spreads to all cutaneous and mucous surfaces by 20 weeks of gestation.[85] The spread of cutaneous sensation is preceded by and synchronized with the development of synapses between incoming sensory fibers and receptive neurones in the dorsal horn of the spinal cord, which first appear during the sixth week of gestation.[125, 192] Rizvi and colleagues have shown that morphologic differentiation of dorsal horn neurons in the spinal cord begins around 13 weeks of gestation.[145] Further development proceeds with their arrangement into Rexed's laminae, together with formation of synaptic interconnections and specific neurotransmitter vescicles to form a mature dorsal horn in some regions of the spinal cord by 30 weeks of gestation.

Traditionally, lack of myelination has been proposed as an index of immaturity in the neonatal nervous system[169] and used frequently to support the argument that neonates and infants are not capable of pain perception.[6] As described above, nociceptive impulses in adult peripheral nerves also are conducted via unmyelinated and thinly myelinated fibers. The slower conduction velocity in neonatal nerves or central nerve tracts resulting from incomplete myelination is offset by the shorter interneuronal and neuromuscular distances that the impulse has to travel in neonates and small infants.[154] Furthermore, using quantitative neuroanatomic methods, Gilles et al. have shown that nerve tracts associated with nociception in the spinal cord and brain stem (the lateral spinothalamic, spinal trigeminal, spinoreticular, dorsal cervical, and spinocerebellar) are completely myelinated up to the thalamus by 30 weeks of gestation.[72] Thereafter, the thalamocortical nociceptive connections via the posterior limb of the internal capsule and corona radiata undergo complete myelination by 37 weeks of gestation. Formation and myelination of the nerve tracts linking nociceptive centers in the brain stem, thalamus, and sensory cortex, with the limbic system, hypothalamus, and associative areas of the cerebral cortex, have not been studied and may occur during early infancy and childhood.

It is clear from the above that the neuroanatomic apparatus for conducting nociceptive impulses from the periphery to the sensory cortex is intact even in the newly born infant (Fig. 2). Development of the fetal

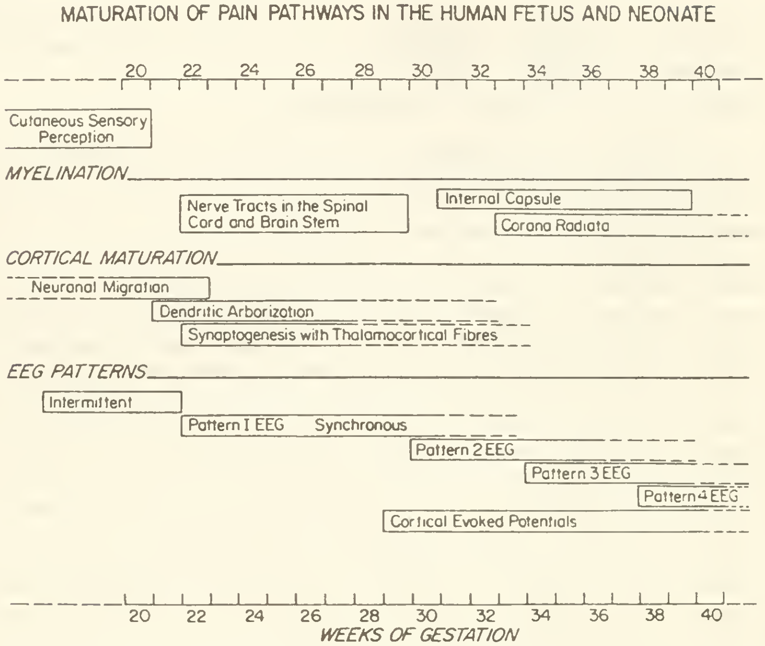

Figure 2. Overview of the development of nociceptive functions and their physiologic basis during the third trimester of fetal life. (*From* Anand KS, Hickey PR: N Engl J Med 317:1321, 1987; with permission.)

neocortex begins at 8 weeks' gestation; by 20 weeks the cortex has a full complement of 10^9 neurons. The dendritic processes of cortical neurons undergo profuse arborization and develop synaptic targets for the incoming thalamocortical fibers and intracortical connections.[117, 143] The development of these connections is of crucial importance for cortical perception because most sensory pathways to the cortex have synapses in the thalamus. From studies on primate and human fetuses, Rakic et al.[143] have shown that afferent neurons in the thalamus produce axons that grow into the cerebrum prior to midgestation and "wait" just below the neocortex until migration and dendritic arborization of cortical neurones is complete. Finally, the thalamocortical connections are established with synaptogenesis occurring between 20 and 24 weeks' gestation.[98, 99]

Several types of observations speak for the functional maturity of the cerebral cortex in the fetus and neonate. First are reports of fetal and neonatal EEG patterns, including cortical components of visual and auditory evoked potentials, that have been recorded in preterm babies of less than 30 weeks' gestation.[60, 170] Recent studies also have identified the cortical components of somatosensory evoked potentials.[96] Second, *in vivo* measurements of cerebral glucose utilization have shown that the maximal rates of metabolic activity occur in sensory areas of the neonatal brain (sensorimotor cortex, thalamus, midbrain–brain stem regions).[42] Third, well-defined periods of sleep and wakefulness are present *in utero* from 28 weeks' gestation, in addition to various cognitive, coordinative, and associative capabilities demonstrated by newborn infants together with their specific behavioral responses to pain. Thus, human newborns do have the anatomic and functional components required for appreciation of painful stimuli.

Further development of the pain pathways during infancy and childhood involves the refinement of these sensory modalities and intracortical connections with the limbic system and the affective and associative areas located in the frontal cortex, parietal cortex, and the insula. The development of descending inhibition of nociceptive neurons and interneurons in the dorsal horn of the spinal cord and the sensory brain stem nuclei also occurs during this period. The importance of this phase of development in the maturation of the pain system is underscored by the high index of "brain plasticity" present during this period. Clearly, the cellular, synaptic, and molecular mechanisms determining brain plasticity are highest during infancy and early childhood.[185] Painful and other experiences during this period therefore may determine the final architecture of the adult pain system, with subtle and presently undefined characteristics responsible for the clinically evident individual variation.

NEUROCHEMISTRY

Taxonomy of Pain Mediators and Transmitters

Pain's complex neurophysiology is the result of mediator molecules or other stimuli acting on nociceptors that evoke subsequent responses within many neural circuits. Dozens of neurotransmitters act within these diverse, multilevel circuits. In the microenvironment of the nociceptor, mediators of injury or inflammation range in size from mere ions such as potassium or hydronium, to simple monoamines such as histamine, to eicosanoids, to peptides such as bradykinin, to proteins such as lymphokines. Each class of mediator occurs centrally in pain pathways, too, as a primary neurotransmitter or as a modulator of underlying synaptic transmission.

Monoamines active in central pain pathways include dietary amines (e.g., glycine) or enzymatically produced derivatives. Tyrosine-derived catecholamines (particularly those such as norepinephrine) that act on presynaptic alpha-2 receptors, and tryptophan-derived serotonin both convey inhibitory brain stem signals to the spinal cord dorsal horn and also contribute to analgesia after opioid administration. Drugs such as clonidine, an alpha-2 agonist, or monoamine oxidase inhibitors, are recognized to be analgesic by virtue of their stimulatory actions upon monoamine analgesic pathways. GABA (gamma-aminobutyric acid), or drugs such as baclofen or midazolam that act on GABA sites, have likewise been found to produce analgesia, largely by acting on the spinal cord.

Peptides have a primary structure made up of a chain of amino acids. These chains twist to produce three-dimensional structures that fit specific receptors in assorted bodily compartments. Understanding of pain and its relief has been revolutionized in the past 15 years by the isolation within the central nervous system (CNS) of multiple peptide families, termed "neuropeptides." Studies from a variety of disciplines delineating the behavioral, biochemical, and pharmacologic effects of such peptides in humans began to appear only within the last decade but are now quite numerous. Taking as criteria for neurotransmitter function 1) the presence of a peptide as assessed by radioimmunoassay, 2) its localization within discrete neuronal populations by immunohistochemistry, 3) its release from neurons *in vivo* or *in vitro* in a calcium-dependent manner, and 4) the presence of specific receptors and cellular actions triggered by receptor occupancy, it is now accepted that a variety of neuropeptides do serve as authentic neurotransmitters. Peptides function in excitatory (e.g., substance P) and inhibitory (e.g., enkephalins) roles at spinal and supraspinal levels. All peptides are biosynthesized from larger precursor forms that are cleaved and otherwise processed to yield active daughter forms.

Although the opioid peptides are certainly the best-studied group of neurotransmitters in the context of pain, much effort recently has been directed to extending the results found with endorphins to other peptide neurotransmitters. It is already clear that certain forms of environmental stress evoke analgesia that is unaccompanied by endorphin secretion and is not reversed by naloxone. Such stress-induced analgesia has been termed *nonopioid*, and certain features suggest mediation by monoamines; yet the roles of many possible nonopioid peptides that might subserve such analgesia remain to be defined. The candidates are myriad because dozens of peptide neurotransmitters, many originally identified outside the CNS (e.g., in gut). Several stand out as most deserving of attention.

Calcitonin was discovered by Copp and co-workers in 1962, and named on the basis of its functional antagonism of the hypercalcemic effects of parathyroid hormone.[19, 87] It is derived from "C" cells of the thyroid gland, and inhibits osteoclastic activity in bone and calcium resorption by the kidney. After it was located in the brain, its brain receptors were demonstrated and physiologic effects of intracerebral administration were examined. Apart from its effects on bone, calcitonin has produced analgesia in patients with cancer and nonmalignant pain such as causalgia or pancreatitis.[175] Prolonged analgesia in tail pinch but not tail flick assays was demonstrated after intracerebral administration of calcitonin to animals. Derived from the same precursor as calcitonin is calcitonin gene-related peptide (CGRP), which has been localized in dorsal root ganglia and substantia gelatinosa, trigeminal ganglion, and other areas that modulate pain.[149] There is some, but not complete, competition between calcitonin and CGRP for brain receptors.

Neurotensin, although its structure was elucidated from hypothalamic extracts, is present outside the CNS in the gastrointestinal tract, and outside the hypothalamus in areas of the CNS important for pain processing such as the periaqueductal gray and superficial laminae of the dorsal horn. As is the case for calcitonin, neurotensin produces modality-specific analgesia in rats: hot plate and acetic acid writhing tests give positive results, but not tail pinch. In mice, neurotensin produces comparable analgesia after intracisternal injection as beta-endorphin.

Corticotropin-releasing factor (CRF) is understood to mean the 41 amino acid hypothalamic peptide characterized in 1981 by Vale and colleagues on the basis of its stimulation of ACTH and beta-endorphin release from the pituitary. Many other compounds, such as vasopressin or interleukin-1, possess such stimulatory activity but are not the "authentic" CRF.[196] CRF neurons are widely distributed in brain areas concerned with autonomic regulation and its intracerebral administration activates the sympathetic nervous system and produces behavioral arousal. Recently Hargreaves, Dubner, and colleagues have shown that peripheral administration of CRF induces analgesia in rats and human subjects.[77]

Somatostatin was isolated in 1973 from hypothalamic extracts by Brazeau and colleagues in a search for inhibitors of growth hormone release. Somatostatin inhibits the release of multiple pituitary hormones besides growth hormone, and its high concentration within the nervous system, particularly in the superficial dorsal horn of the spinal cord, led to tests of its analgesic potential.[66] Rats are more sensitive to the toxic effects of somatostatin than are species such as the dog, rabbit, or (apparently) human because a number of studies in postoperative pain in humans have proceeded apparently without incident.[41] Analgesia produced by somatostatin is more pronounced for pinprick testing than cutaneous thermal pain and is not reversed by naloxone nor associated with respiratory depression.

Substance P was isolated decades ago by von Euler and characterized 20 years ago by Leeman and colleagues. Its importance as a neurotransmitter for primary nociceptive afferents is by now well accepted and has led to synthesis and testing of antagonist compounds. Likewise the "gut" peptide cholecystokinin (subsequently identified in brain) appears to be hyperalgesic: it is contained in the same neurons within the dorsal horn as substance P and antagonizes analgesia produced by opiates.[154]

This summary cannot do justice to a vast and actively evolving literature; for conciseness references are given to recent reviews or monographs,[136, 194, 195] each of which deals with multiple nonopioid analgesic peptides.

Opioid Receptors and Ligands

Cellular receptors for morphine were postulated some time ago (Portoghese 1960), and the existence and functions of multiple types of opiate receptor were deduced with great precision by Martin in the 1970s.[71, 113] (Martin had himself speculated in the 1960s that "one can assume, for argument's sake, that opioids mimic a naturally ongoing process."[112]) His seminal studies, although performed in dogs, were prompted by clinical impressions of different symptoms displayed by narcotic addicts during exposure to or withdrawal from opiates that had different structures. His observations were based solely on *in vivo* effects: no effort was made to physicochemically analyze any receptor. Nevertheless, his classification is still current, albeit with interim refinements. Thus, the receptor most readily activated by morphine—to produce analgesia, mydriasis, and respiratory depression—was named *mu*. Ketocyclazocine produced analgesia with less respiratory depression than morphine by acting on a postulated "kappa" receptor. The proprietary compound SKF 10,047 (N-allyl normetazocine) produced excitation but little analgesia and was deemed "sigma" receptor selective.

Martin's classification, based on work in his laboratory at an addiction research facility in Kentucky, was extended by results obtained by another long-standing addiction research group in Aberdeen, Scotland. The Scottish investigators had isolated and characterized the structure of two pentapeptides, leucine and methionine enkephalin, by tracking opiate activity of successively purified pig brain fractions.[84] To monitor opiate activity they measured analytes' inhibition of electrically induced smooth muscle contraction. Armed with a test drug panel composed of the enkephalins, related peptides, and morphine, they found different potency rankings for drugs tested in their bioassay, depending on whether the smooth muscle was harvested from guinea pig ileum or mouse vas deferens.[106] They deduced that opiate receptors in mouse vas deferens must be distinct from those in guinea pig ileum (which were already recognized to be mu-like), and gave the name *delta* to this newly recognized opiate receptor.

By the start of the 1980s, laboratories throughout the world had confirmed the division of opiate receptors into at least four major categories by methods such as numerical analysis of drug-receptor binding, displacement of reference reagents by test compounds, susceptibility to naloxone reversal of drug effects, and quantitative autoradiography.[35, 201] These methods, increasingly removed from Martin's clinical starting point, have further disclosed subtypes within major receptor categories.[29, 30] Pasternack's identification of high-affinity mu_1 and low-affinity mu_2 receptor subtypes is especially promising because of experimental evidence *in vivo* that opiate analgesia is mediated by the former receptor subpopulation, whereas activation of the latter produces undesirable side effects, such as respiratory depression.[129]

One of the most powerful tools for studying opiate receptors—not to speak of endorphin physiology in general—has been the ongoing characterization of their endogenous ligands. Strong homologies in the amino acid sequences of the opioid peptides created initial confusion in the 1970s as to the number and distribution of opioid peptides. By the early 1980s this confusion was overcome by consolidation of results from peptide chemistry, immunologic analyses relying on region-specific antibodies, and, ultimately cloning and sequencing the genes for their precursor molecules.[30, 47, 94, 148] The three precursor molecules, named according to their biologically active fragments, are proenkephalin, pro-ACTH/endorphin (or, synonymously, pro-opiomelanocortin [POMC]), and prodynorphin. The name of the second precursor derives from the remarkable fact that ACTH and beta-endorphin are cosynthesized from a common parent molecule[53] and cosecreted during stress (see later).

Opioid Analgesia

The likelihood that "morphine appears to enhance supraspinal inhibitory mechanisms on pain reflexes" was mentioned by Beecher in the 1950s.[17] Subsequent work by several groups revealed that morphine does activate supraspinal neurons that descend to inhibit pain transmission through the spinal cord.[116, 186, 193, 195] Direct measurements of spinal cord neuron responses to pain, their inhibition following systemic doses of morphine, and the reduction of this morphine effect after spinal cord transection[76] further confirmed this view. The identification of opiate receptors prompted Basbaum and Fields to mold their own and others' findings into a unified "descending opiate-mediated analgesia system."[16] In this model, the periaqueductal gray of the midbrain and the raphe and adjacent nuclei in the medulla are densely supplied with opiate receptors, and in turn descend via dorsolateral tracts to inhibit the dorsal horn. As might be surmised from the above work, opiate receptors in this system (e.g., periaqueductal gray) are predominantly mu. Because spinal transection does not reduce kappa agonists' analgesic effect at the level of the distal cord (Wood 1981), kappa receptors appear less active in this descending analgesic pathway. Descending endorphin-mediated analgesic pathways, normally quiescent, become active during many forms of external threat or insult to produce "stress-induced analgesia."[93, 171]

Although the peripheral actions of opiates require more characterization, spinal mechanisms of opiate analgesia have been explored in meticulous detail for decades.[186, 195] Just as new findings of the past 15 years have enhanced (but not overthrown) prior knowledge of opiate structure–function relationships or neuroendocrine stress responses, so have advances in endorphin biology been fruitfully applied to clarify clinical and basic aspects of spinal opiate analgesia.[94, 116, 193] For example, all drugs active as opioids are now recognized to share key stereotopic determinants.[168] The presence of opioid peptides and receptors within the dorsal horn was confirmed as soon as methods appeared for doing so,[12] and considerable detail was added as multiple opioid peptides and receptors were distinguished and exploited clinically.[46, 83, 194] There is now no question that multiple opiate receptors at the spinal level participate in a complex filtering process, in which distinct opiate receptors act selectively to impede pain signals arising from different forms of injury.[190]

Opioids have unique actions in the dorsal horn.[51, 52, 79, 156, 195] Applied systemically or spinally, opioids reduce neurotransmitter release (e.g., of substance P) into synapses of primary afferents and also shrink the size of cutaneous receptive fields evoked by A-delta and C-fiber impulses, without affecting responses evoked by A-beta afferents. Opioids inhibit responses to C-fiber stimulation more so than to A-delta stimulation. Most significantly, opioids reduce the rate of rise of the excitatory postsynaptic potential (EPSP) that normally results from prolonged C-fiber input, thereby blocking dorsal horn neuronal excitation in response to this input. This action on EPSPs occurs at low doses of morphine and is manifest *in vivo* as the prevention of flexor reflex conditioning by C-fiber afferent stimuli.[45] Tenfold higher doses of morphine are required to reverse this C-fiber facilitation of reflex withdrawal once it is established.[191] Opioid inhibition of dorsal horn EPSPs may underlie two recent important clinical observations: first, recruitment of additional dermatomes of sensory *anesthesia* by systemic morphine during epidural infusion of local anesthetic,[109] and second, forestalling of postoperative pain by the combined technique of opioid premedication plus local anesthetic nerve blocks.[114, 179]

Mu, kappa, and to a lesser degree, delta receptors are concentrated within the spinal cord gray matter, particularly in the dorsal horn.[116, 129, 193] Their greatest densities are in substantia gelatinosa, at the "gate" postulated by Melzack and Wall to regulate nociceptive input, as well as in deeper layers (Rexed IV-VI) termed the *nucleus proprius*. Selective activation of mu receptors markedly reduces visceral pain, or acute pain caused by exposure to heat, but is less effective against pain from skin (or tail) pinch.[172, 173] Kappa agonists (i.e., agents which bind to and activate kappa receptors) in contrast are more potent than mu agonists at reducing pain caused by pinch, hardly effective at all on thermal testing, and comparably analgesic for pain due to peritoneal irritation. Delta agonists are, like mu agonists, active against thermal pain, but basic and clinical reports point to their effectiveness against visceral pain as well.[26, 126, 142, 153]

Despite the above unresolved issues, the recognition of multiple receptor types has at least shed light on how one might select a narcotic painkiller by matching it to the mode of pain to be treated. A wide[29, 61, 63] and increasing[26, 40, 126] range of clinically useful opiates now includes selective agonists of varying duration (e.g., fentanyl and alfentanil, which selectively activate mu receptors for longer or shorter intervals); partial agonists (e.g., buprenorphine on mu receptors); and mixed agonist–antagonists. The latter type of compounds, typified by butorphanol or nalbuphine, act as agonists on one opiate receptor type and simultaneously as antagonists on another. Recently the latter compounds have been given to reverse respiratory depression following intraoperative use of a mu agonist: they stimulate ventilation by blocking mu receptors, yet maintain analgesia through kappa receptor activation.[200] Unfortunately, patients habituated to chronic use of a mu agonist such as morphine or methadone may undergo acute narcotic withdrawal when first exposed to agonist–antagonist drugs (including pentazocine).

Neurotransmitter Expression in the Fetus

Several mediators, including the various classes of neuropeptides, monoamines, and catecholamines, described above, act as neurotransmitter and neuromodulator substances in the central nervous system. Thus, A-delta and C-fibers related to afferent pain pathways may contain substance P, somatostatin, CGRP, vasoactive intestinal peptide (VIP), and glutamate. Enkephalin-containing fibers are localized in the dorsal horn of the spinal cord, whereas 5-HT, norepinephrine, and dopamine are contained in fibers descending from the brain stem that terminate in the dorsal horn. In the human fetus, fibers containing CGRP, somatostatin, and substance P appear in the dorsal horn at 8 to 10 weeks' gestation.[36, 38, 111] Mediators such as enkephalin and VIP appear later, at 12 to 14 weeks' gestation.[37, 39] The density of all these peptides increases gradually during gestation with marked increases around the perinatal period. On the other hand, 5-HT has not been detected in the spinal cord of human fetuses or neonates and is thought to develop some time after the first 6 postnatal weeks.[111] Catecholamines and other monoamines were observed in the dorsal horn during late gestation and early infancy, having appeared earlier in the ventral and intermediate regions of the spinal cord.[111] Substance P-positive fibers and cells also were observed in areas of the brain stem and higher centers associated with nociception and endogenous antinociception, although the significance of this distribution is unclear.[50, 123, 130, 137]

Endorphinergic cells have been observed in the anterior and intermediate lobes of the fetal pituitary gland[15, 104] and were responsive to CRF stimulation *in vitro* by 20 weeks' gestation.[70] Increased production of beta-endorphin during fetal and neonatal life was demonstrated subsequently by a beta-endorphin/beta-lipotropin molar ratio of 0.36 in adult pituitary glands, 1.04 in neonatal and 2.13 in fetal pituitaries.[177] Endogenous opioids are released in the human fetus at birth and higher levels are found in response to fetal and neonatal distress, birth asphyxia, infections, and in newborns of drug-addicted mothers.[81, 125, 139, 162] It has been speculated that elevated beta-endorphin levels may be responsible for decreased anesthetic requirements in neonates,[103] although we may caution that the concentrations of beta-endorphin during analgesia after injection into the CSF of human adults[60] were more than 10,000 times greater than the highest values recorded in neonatal CSF or plasma.

CLINICAL IMPLICATIONS

The above background has significance primarily as a biologic framework within which the management of pain in pediatric patients can be defined. The detailed clinical application of this information is elsewhere in this volume, in which pharmacotherapy, behavioral approaches, and special settings such as the neonate or postoperative period are discussed. To describe the clinical sequelae of analgesia or its absence, this section describes the context in which stress responses are evoked by nociceptive mechanisms or blunted by analgesics, and exert their clinical effects through a variety of physiologic systems, such as neuroendocrine and cardiovascular. In this context the results of a variety of studies arguing for aggressive analgesia in pediatric patients may then be reviewed.

Pain, Analgesia, and the Global Stress Response

Clinical management of two hallmarks of the global stress response is key to the optimal outcome of illness in the neonate, infant, and child. First is its neuroendocrine dimension, in which a coordinated outpouring of pituitary, adrenal, and pancreatic hormones may grossly disturb protein and carbohydrate metabolism in the perioperative period. Second are cardiovascular reactions manifest as arrhythmias and diminished perfusion of vital or healing organs. Other aspects of the global response, such as altered immunity or respiratory effects, are of course significant, but the first two areas stand out as those in which integration of basic and applied science has had an impact on daily clinical practice. Since these two types of response are known from clinical studies (see later) to respond favorably to the administration of opioids, we shall focus on the mechanisms by which opioid analgesia produces its favorable clinical effects in these contexts.

How Do Opioid Analgesics Blunt Neuroendocrine Responses?

Morphine and fentanyl exert their global effects at multiple levels within highly organized, often intricate regulatory pathways that receive

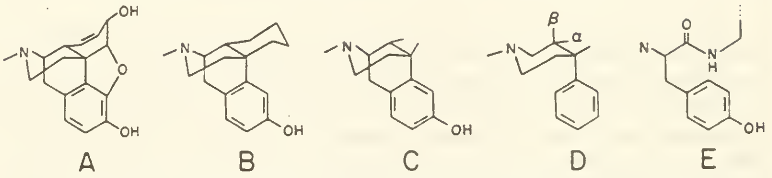

Figure 3. Common structural features of morphine (a), morphinan (b), benzomorphan (c), phenylpiperidine, (d) fentanyl, and enkephalin, (e) molecules. (*From* Carr DB: Opioids. Intl Anesth Clin 26:273, 1988; with permission.)

and integrate nociceptive inputs. From these pathways emanate neural outflows to distinct organs and circulatory beds, and nociceptive signals that ascend rostrally to influence emotion, perception, and hormone secretion from the pituitary and adrenal glands. Some evidence suggests analgesic effects of opiates in the periphery as well, outside the CNS. It is not surprising, then, that in broad terms the effect of intraoperative opiate analgesia is to diminish the magnitude of stress hormone secretion—particularly adrenocortical and adrenomedullary—by diminishing nociceptive input, as well as the centrally mediated neuroendocrine response to a given level of such input. The introduction of modern radioimmunoassay methods, beginning in the late 1960s as opioid "anesthesia" was developed,[107] was indeed soon followed by reports that stress hormonal responses to surgery were more effectively suppressed by high doses of opioids than by inhalational agents.[20, 68, 75, 122, 136, 163]

In fact, morphine was employed decades ago to probe pituitary physiology.[15, 21] It was given by itself or with barbiturates to inhibit CNS input to the pituitary gland and thereby pharmacologically to isolate the latter from its hypothalamic nerve supply.[196] For this reason, and also from pursuit of explanations for endocrine dysfunction in narcotic addicts,[21] abundant knowledge already existed in the pre-endorphin era concerning the hormonal effects of narcotics.[199] Morphine, for example, provokes prolactin release in humans, and inhibits the secretion of pituitary gonadotropins—actions that mimic the pituitary response to environmental stress. Morphine's effects are mediated not by direct actions upon the pituitary, but rather on its neural input (i.e., the hypothalamus).[33, 199]

Once opiate receptors and their endogenous ligands were recognized as the biologic basis for prior findings based on morphine, research in this area promptly advanced along several avenues. First, responses to naloxone at baseline and during a variety of stressors by subjects who were narcotic free permitted inferences as to the actions of endogenous opioids and their receptors in such circumstances.[22, 118, 141] Naloxone, like morphine, is an alkaloid (in contrast to endogenous opioids that are peptides) and hence has some biologic effects not mediated solely through opiate receptors.[152] Nonetheless, responses to naloxone, morphine, and synthetic opioid peptides are for the most part consistent and complementary.[60, 118, 141, 152, 165] Second, echoing events in pain research, the anatomic substrate of morphine's endocrine effects—particularly the hypothalamus—was found to have high concentrations of opioid receptors, which were of multiple functional types.[33, 129, 133, 201] Each receptor type and subtype had somewhat different actions on hormone secretion, making it possible to tease apart, using selective agonists or antagonists, the regulation of individual stress hormones within the global stress response.[56, 97, 131, 132, 134, 162] Third, the discovery that beta-endorphin and ACTH arise from the same parent molecule[53] suggested that endogenous analgesia, and the autonomic and endocrine responses to stress were one seamless garment with common molecular threads. Unfortunately, although the foregoing may be true in a general sense, levels of one and the same opioid peptide may change in the same or opposite directions in separate compartments (e.g., cerebrospinal fluid, plasma, brain nuclei. . .) or have no apparent relationship, depending on the particular stress or species studied.[31, 190] Furthermore, the anatomic distributions of the three opioid peptide families[145] do not coincide: neurons containing ACTH and beta-endorphin are found in the hypothalamic arcuate nucleus, and brain stem vagal nuclei, whereas the other two families of neurons are more diffusely distributed throughout the nervous system.[89, 94, 116, 153]

A major source of confusion in interpreting opioid effects on stress hormone secretion, enunciated over 30 years ago, is "the apparent paradox that morphine can stimulate, as well as depress, the release of ACTH."[21] If one considers, however, that pituitary secretion of any hormone normally reflects a balance between stimulatory and inhibitory signals from hypothalamus, and that the hypothalamus itself receives dual inhibitory and stimulatory projections from multiple brain areas, this apparent paradox is more understandable.[13, 31, 196] For example, surgical stress[65] activates brain stem and limbic neural pathways, which stimulate the hypothalamus to secrete CRF and other hormones (e.g., vasopressin) that act to trigger pituitary ACTH and beta-endorphin release.[196] Opioids, as analgesics, reduce nociceptive afferent traffic reaching the hypothalamus[116, 156, 157, 193, 194]; opioids as hypothalamic hormones lessen the CRF response to such neural traffic as remains.[135, 196] In the latter context opioids alter synaptic transmission in monoamine circuits of the hypothalamus,[160] an action termed *neuromodulation*.[90] Thus in crude terms opioids may be likened to a car's brakes: unimportant unless the car is moving.

These dual, superficially contradictory influences of opioids on hormone secretion are evident for most pituitary stress hormones as well as plasma catecholamines.[32] Systemic opioids stimulate CRF (and hence adrenocortical) secretion when given to unstressed subjects[54, 131] but inhibit the corticosteroid increase during surgical or other stresses. Interestingly in view of vasopressin's physiologic action as a CRF-like hormone, morphine and other opioids tend to raise its levels in basal subjects but inhibit its stress-induced rise. Systemic opiates, or intracerebral beta-endorphin, increase plasma catecholamines if given under basal conditions[174] but act upon stimulatory circuits in hypothalamus and brain stem to reduce the normal catecholamine rise produced by a variety of stresses.

Thus, in their dual roles during stress, endogenous opioids regulate the responses of many hormones and themselves are secreted to produce a host of biologic effects. Morphine, fentanyl, or synthetic opioid peptide administration mimic the actions of endorphins on their receptors,[27] and through feedback controls typical of endocrinology reduce endogenous opioid secretion during stress. Endorphins participate in many instances of stress-induced autoanalgesia, and measurements of plasma endorphin concentrations at times provide a rough index of activity within central opioid pathways.[110, 127] Clinical reports have related such plasma measurements to pain after surgery or trauma,[44, 167] but the many dynamic components of the endorphin system, intricately arrayed within many compartments, frustrate unidimensional "dipstick" measurements or reductionist attempts to depict their role in simple terms.

Pain, Opioid Analgesia, and Cardiovascular Stability

Holaday has pointed out that the cardiovascular actions of opioids were probably first noted when someone who had received opium stood up and felt dizzy.[82] Cardiovascular sequelae of opioid use have been analyzed for over a century, and the continuing appearance of reviews from differing perspectives shows the area is still a thriving one.[27, 57, 82, 88, 147] As traced above for pain and hormone secretion, research in the last 15 years has extended earlier work without negating it. For example, Gann and associates had earlier mapped with great precision the central pathways linking cardiovascular afferents with ACTH secretion.[64]

Based on a review of studies such as these, and their own results, Randich and Maixner have convincingly argued that "systems controlling cardiovascular function are closely coupled to systems modulating the perception of pain."[144] We might well carry their thesis further, to state that the anatomic substrates for opioid actions in any physiologic system—nociception and stress hormone secretion being but two examples—bear striking parallels and at points literally coincide. In each instance examples may be cited of 1) excitatory effects of exogenous opioids given to resting subjects contrasting with inhibitory effects when identical drugs are given during stress; 2) dense concentrations of opioid receptors and opioid peptides centrally, at sites of intense afferent integration; 3) separate roles for individual opioid peptides and receptor types; and 4) neurally based circuitry that relies heavily on opioid pre- and postsynaptic inhibition of underlying monoaminergic excitatory synapses. How well do opioid cardiovascular effects fall within this scheme?

Morphine, if given to normal subjects in the basal state, may produce tachycardia and increase ventricular contractility via a reflex sympathetic activation that can be prevented by beta-adrenergic blockade.[147, 176] In contrast, under conditions of high initial sympathetic tone, morphine decreases blood pressure by producing a centrally mediated sympatholysis.[107, 108] These effects may be exaggerated by morphine's propensity to release histamine if administered quickly, but similar findings occur with fentanyl, for which histamine release is not an issue.[146] The excitatory effect of morphine in unpremedicated normal subjects may reflect acute CRF release, which is known to produce sympathetic activation, or effects on spinal sympathetic effector neurons.[62, 155] The inhibitory effect of morphine on preexisting sympathetic activation may reside in the paraventricular nucleus of the hypothalamus (a key site for integration of neuroendocrine and autonomic responses[166] or the locus coeruleus,[1] from which most brain noradrenergic projections originate.

Opioid receptors were early demonstrated in the vagal nuclei,[12, 94, 193] and the vagotonia that opioids cause daily in the operating room is well explained by their binding to these sites to stimulate parasympathetic outflow.[67, 100] A prolonged bradycardia (after an initial transient tachycardia!) has in fact been observed after intracerebral administration of several opioid peptides.[74] Vagal outflow appears to underlie the protective effect that morphine exerts against ventricular fibrillation, as this protective action is lost after atropine or vagotomy.[49] Fentanyl also exerts a protective effect against ventricular fibrillation; this effect is significant during stress but not under basal conditions, is lost after vagotomy, but is unaffected by atropine.[151] Fentanyl's actions thus depend on vagal afferent traffic and accord with the profibrillatory effect of naloxone,[115] as well as the actions of other protective agents, which likewise appear to enhance the brain stem baroceptor reflex.[34] This reflex receives baroceptor impulses entering via the vagus and responds to blood pressure rises by decreasing sympathetic and increasing parasympathetic efferent traffic, thereby slowing the heart rate.[153] Its enhancement by opioids is the basis for these agents' "vagotonic" action. As this discussion suggests, opioid agonists with different receptor specificities have distinct cardiovascular actions. Paralleling research on nociception and hormone release, a variety of workers have shown that multiple opioid receptors have distinct roles in cardiovascular regulation. This is certainly so in shock states[82] and has been accepted in basal studies as well.[55–57, 76, 135]

As to the last portion of our opioid paradigm, opioids enhance contractility in isolated myocytes,[101, 102] whereas in preparations in which cardiac innervation is preserved, they oppose catecholamine-induced contractility and chronotropy.[23–25, 43, 105, 150] This anticatecholamine, modulatory effect is evident when probed, using the beta-adrenergic agonist isoproterenol,[25, 43, 150] and it is associated with a reduction in the normal calcium influx that ordinarily follows isoproterenol binding to myocardium.[102, 150] Conversely, peripherally administered opioid receptor antagonists such as naloxone or nalmephene acutely increase myocardial inotropy and chronotropy.[23–25, 105] The latter effects are particularly strong after acute bilateral carotid occlusion[25] or after tricuspid avulsion and progressive pulmonary artery constriction,[105] both conditions in which blood pressure is maintained by sympathetic outflow. These results in the periphery echo morphine's exaggerated, centrally mediated reduction of blood pressure in patients[107] or animals[105] with elevated resting sympathetic tone. The circuitry by which these peripheral effects occur—inhibition of underlying catecholamine neurotransmission—mirrors that in many sites within the CNS, in which for example opioids inhibit substance P release (in dorsal horn of spinal cord), dopamine release (in hypothalamus or basal ganglia), or norepinephrine release (from locus ceruleus). Whether physiologic levels of opioids confer protection from harmful effects of circulating catecholamines (e.g., patchy necrosis) during circulatory compromise, or decrease inotropy or chronotropy enough to exert a protective effect on myocardial oxygen consumption is speculative, although drugs that directly block beta-receptors or calcium channels are given clinically for such purposes.

Pain and Metabolism: Clinical Studies

Studies in adult patients undergoing surgery have shown that injury triggers the release of "stress hormones" (catecholamines, corticosteroids, growth hormone, and glucagon), which stimulate a cascade of metabolic changes leading to substrate mobilization with the breakdown of protein, fat, and carbohydrate stores. These metabolic changes are one component of the global response which, in a nonhospital setting, may facilitate wound repair and eventual recovery.[5] In a hospital setting these responses serve no useful function and following severe trauma may lead to a hypermetabolic state associated with complications such as cardiac insufficiency, dysrhythmias, and myocardial infarction, pulmonary insufficiency, impaired immune responses, thromboembolic complications, gastric stress ulcers, persistent metabolic acidosis, and prolonged convalescence in adult patients.[92] Moyer et al. measured metabolic stress responses in adult patients with sepsis and trauma and were able to discriminate between patients who survived and those who did not survive with 99 per cent certainty up to 9 days before death.[120] In some cases, a severe catabolic drive may persist even after subsidence of the stressful stimulus that triggered it, and may prevent the healing and repair of injured tissues.

As a result of these data, anesthetic techniques have been developed for decreasing the stress responses to major surgery. Suppression of stress responses in adult patients using high-dose opioid[107] or epidural anesthesia,[197] both of which would abolish perioperative pain, have shown a significant reduction in postoperative morbidity and mortality. Based on these data, it is reasonable to expect that similar beneficial effects may be obtained by decreasing the stress responses of neonates and children. One might further surmise that the current practice of limited perioperative analgesia in pediatric patients may result in an exaggerated stress response and contribute to an increased incidence of postoperative complications and poor clinical outcome following major surgery.

In pediatric patients, and particularly newborn infants, metabolic stability is much more difficult to maintain because of: 1) a relatively greater surface area, necessitating greater heat production; 2) a larger brain-to-body weight ratio, with increased obligatory requirements for glucose; 3) the need to maintain somatic growth; 4) much smaller reserves of protein, carbohydrate and fat; 5) metabolic adaptation to extrauterine life and enteral nutrition; and 6) maturation of metabolic enzyme systems and homeostatic mechanisms controlling these systems.[4, 14] Given the physiologic and metabolic immaturity in early life, it is not surprising that a high incidence of postoperative complications and mortality have been documented in neonates and critically ill children undergoing major surgery.[95, 164] Despite their clinical importance, there are few published data on the stress responses of pediatric patients undergoing anesthesia and surgery.[11]

Preliminary studies showed that neonates responded to surgical stress with marked increases in plasma catecholamines, glucagon, and glucocorticoids, together with suppression of insulin secretion. These hormonal changes precipitated hyperglycemia and lactic acidosis, associated with other indices of metabolic substrate mobilization.[11] Older infants and children also had similar hormonal changes, although their catecholamine and glucagon responses were smaller than in neonates, and their cortisol responses were greater and more prolonged than in neonates. These stress responses differed quantitatively, and in their time course in relation to surgery, from those of adults. In general, hormonal–metabolic changes in infants and children were greater in magnitude than those of adult patients, particularly with regard to the increases in plasma epinephrine, glucagon, growth hormone, blood glucose, blood lactate, and other gluconeogenic substrates during and after surgery. Infants and children mounted uniphasic cortisol responses which were smaller than the marked biphasic responses of adult patients undergoing surgery, and plasma insulin decreased to lower values both during and after surgery as compared to adult patients. Important differences were therefore evident between the pediatric and adult stress responses following surgery.

The effects of anesthesia on the neonatal and pediatric stress responses are important and may contribute to the effects of stress suppression on postoperative clinical outcome. In a randomized controlled trial, preterm babies undergoing ligation of the patent ductus arteriosus were given nitrous oxide and curare, with or without the addition of intravenous fentanyl. Marked hormonal responses to surgery, as indicated by changes in plasma epinephrine, norepinephrine, glucagon, aldosterone, corticosterone, and other steroid hormones, were decreased significantly in neonates receiving fentanyl. The hormonal responses of neonates receiving nitrous oxide alone were associated with significant increases in blood glucose, lactate, and pyruvate; these were prevented in neonates given fentanyl in addition.[9] Increased endogenous protein breakdown and an increased incidence of postoperative complications after surgery were also noted in the nitrous oxide group, as compared to the fentanyl/nitrous oxide group.

Another randomized controlled trial compared term neonates undergoing surgery with nitrous oxide and curare with those receiving halothane added to the anesthetic regimen.[10] Neonates given halothane and nitrous oxide anesthesia showed decreased hormonal responses to surgery from those of neonates given nitrous oxide alone, with significant differences in the plasma epinephrine, norepinephrine, and cortisol responses during and after surgery. Changes in circulating concentrations of glucose, nonesterified fatty acids and ketone bodies also were decreased in neonates receiving halothane anesthesia, together with a decreased incidence of complications during and after surgery. These investigations showed that lack of potent anesthesia may be partially responsible for the exaggerated stress responses of neonates reported in earlier studies and suggested that giving deeper anesthesia to neonates undergoing surgery may improve postoperative clinical outcome.

The latter hypothesis was tested in a randomized trial of high-dose opioids in neonates undergoing cardiac surgery. In this study, 15 neonates given halothane and low-dose morphine mounted substantial catecholamine, endorphin, and glucagon responses during and after cardiac surgery; these responses were significantly blunted in another 30 neonates given high-dose sufentanil. Metabolic stress responses between the two groups were also strikingly different, with marked hyperglycemia, lactic acidosis, and substrate mobilization in the halothane–morphine group, which were substantially reduced in neonates given high-dose sufentanil.[6, 7] Major postoperative complications and mortality were more common in neonates given halothane and low-dose morphine than in neonates given sufentanil, in whom no postoperative deaths occurred (Anand KJS, Hickey PR: Unpublished data, 1988). Thus, aggressive anesthesia not only decreased the stress responses of neonates undergoing surgery but also improved their postoperative clinical outcome. From the physiologic rationale presented above, it is likely that similar effects may be expected in older infants and children undergoing surgery, as well as those subjected to artificial ventilation and frequent invasive procedures during intensive care.[59]

Relatively few studies have compared the hormonal–metabolic stress responses of older infants and children receiving different anesthetic techniques during surgery; randomized controlled trials to examine these differences are even fewer. The effects of potent anesthesia on the cortisol responses of infants undergoing abdominal surgery were investigated in a nonrandomized study, which found that infants given nitrous oxide anesthetic mounted significantly greater cortisol responses than did infants given halothane in addition.[124]

In older children, Sigurdsson and co-workers found that morphine and hyoscine premedication in addition to diazepam significantly decreased cortisol, 17-hydroxyprogesterone, and ACTH responses and virtually abolished the catecholamine responses to surgery.[158] A subsequent randomized trial showed that the plasma catecholamine responses to adenoidectomy were significantly greater during halothane anesthesia than during enflurane anesthesia.[159] These differences occurred in both intubated and nonintubated children undergoing adenoidectomy; lower catecholamine levels in the enflurane anesthesia group were associated with a lower incidence of cardiac arrhythmias during surgery.[157]

In infants and children aged 5 to 60 months undergoing pelvic surgery, the neuroendocrine responses during halothane/nitrous oxide anesthesia were abolished completely by epidural anesthesia. Measurements of plasma beta-endorphin, ACTH, arginine vasopressin, and blood glucose levels at 5 and 15 minutes after incision were significantly different between the two anesthesia groups. Plasma cortisol concentrations were unchanged from baseline in both anesthetic groups, presumably because of the short period for blood sampling after the start of surgery.[69] In older children receiving either epidural anesthetic or etomidate during major abdominal operations, the former technique abolished intraoperative adrenocortical stress responses.[121] Plasma concentrations of cortisol, aldosterone, and precursor steroid hormones decreased in children receiving epidural anesthesia, and children given etomidate had decreases in cortisol levels, but with substantial increases in the precursor steroid hormones consistent with impairment of steroid biosynthesis by etomidate. Further studies will be required to demonstrate conclusively an improvement in postoperative outcome in children after aggressive anesthesia and analgesia. Nevertheless the data reviewed above have important implications for the practical management of pain in neonates, infants, and children undergoing surgery.

CONCLUSION

Studies relevant to nociception and its consequences in the very young have proliferated in recent years and the above review can only survey a rapidly evolving field. Despite the promise of continued scientific advances, certain fundamental questions lie outside the realm of clinical investigation per se. For example, questions regarding quality of life are often posed for the adult patient with pain, for example, due to cancer. In those settings, the patient's verbal description is heavily weighted, as are his or her functional abilities as a family member and productive individual within society. Defining quality of life in normal neonates, particularly if premature, is infinitely more difficult given their inability to express or otherwise convey experiences and emotions. Furthermore, "purposeful activity" is a concept that is irrelevant to the neonatal setting.

Despite these difficulties, one must take into account the neonate's potential to grow and develop, to overcome handicaps, and to experience life to a degree far greater than in the adult. To foster optimal development, stress during the perioperative period or prolonged intensive care should be minimized.[3] The recognition of highly developed nociceptive systems, and evidence for clinical, physiologic, and psychologic sequelae of inadequately treated pain in neonates and children, mandate that aggressive treatment of pain is central to such care. In the future, knowledge of nociceptive mechanisms and their ontogeny in the human undoubtedly will be exploited to apply novel treatments of pain in a context-dependent manner. As this occurs, the present perspective that pain and suffering are inevitable parts of each child's illness will have to be abandoned.

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THE LANCET

Pain, Anaesthesia, and Babies

THE provision of adequate anaesthesia for premature and newborn infants has been the subject of considerable debate in Britain in the past few months.[1-4] Similar interest in the topic in the United States stemmed from a mother's letter to *Birth* magazine about her child's "anaesthetic", which consisted of muscle relaxants and oxygen.[5-8] The American Academy of Pediatrics subsequently reviewed anaesthetic practices, and *Anesthesiology* is to respond by way of an editorial.[9] Much of the public interest in the UK was initiated by the paper in our columns (Jan 31, p 243) by Anand and colleagues who looked at the hormonal and metabolic responses to surgery in two groups of preterm infants undergoing ligation of patent ductus arteriosus. One group received 50% nitrous oxide as an anaesthetic while the other received nitrous oxide and fentanyl 10 µg kg. These workers showed a significant reduction in the responses in the fentanyl group, and suggested there was evidence that the postoperative course of that group was more stable.

The study by Anand et al is valuable in that it documents that preterm infants have a catabolic response to surgery, and that this response can be reduced by the use of narcotic analgesics. However, there are some omissions in the paper. No record of intraoperative blood pressures is provided; these values would have given a more reliable indication of level of anaesthesia than heart rate, since the baroreceptor responses are easily suppressed in preterm infants.[10] Anand and co-workers also do not state whether the infants were normocapnic or hypocapnic during anaesthesia. Hyperventilation reduces the MAC (minimum alveolar concentration, a measure of anaesthetic potency) of nitrous oxide in babies and this might have affected the results of the trial. Finally Anand et al infer a better postoperative clinical course in the fentanyl group, although they do not state whether the two groups were matched for severity of illness preoperatively.

It is unfortunate that Anand and colleagues have been criticised for carrying out this study, because despite these shortcomings, it is important. They have been criticised not on the basis of scientific content, but on the grounds that it was unethical to subject babies to surgery without adequate anaesthesia.[4,11] A press release by the All Party Parliamentary Pro-Life Group to this effect[4] is irresponsible. This statement and widespread and largely uninformed press publicity are both inaccurate and damaging. The use of hyperbole and excessive language ("barbarous", "extreme pain", "agony"[4]) in the press release does little to add credibility to its contents. It states that the infants were given "only nitrous oxide (laughing gas)", but fails to point out that nitrous oxide *is* an anaesthetic *and* an analgesic, and that used in the given concentration (50%) in combination with hyperventilation is regarded by many as an adequate anaesthetic. It states that the purpose of the trial was "to test the hypothesis that preterm infants were incapable of feeling pain"—also inaccurate. Anand and co-workers' stated aim was "to investigate the hypothesis that the '*surgical stress responses*' of preterm babies receiving fentanyl anaesthesia are no different from those of newborn babies anaesthetised conventionally with nitrous oxide and curare". There is no mention of whether babies are or are not capable of *feeling* pain. The authors of the press release clearly do not understand the difference between "adequate" anaesthesia and "stress-free" anaesthesia or that the occurrence of hormonal and metabolic responses to surgery is not synonymous with the infant "feeling" pain. In another study[12] Anand et al documented

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metabolic responses in newborn babies given halothane and nitrous oxide, and few would argue that this regimen did not constitute adequate anaesthesia It is also important to note that in the fentanyl non-fentanyl study, the postoperative glucose, lactate, and pyruvate levels were still lower than preoperative values in the non-fentanyl group, even though they were higher than those in the fentanyl group. These findings imply that the nitrous oxide had imparted some benefit, albeit not as great as that of fentanyl.

All the publicity has focused attention on the currently accepted anaesthetic practices with this group of patients. Parents in particular will be anxious to know that their children are adequately anaesthetised. What constitutes "adequate anaesthesia" is difficult to define, but there will be considerable pressure for anaesthetists to use more potent agents than nitrous oxide, because reduction of the metabolic response to surgery might well improve the postoperative course of a very sick preterm infant It is clear that some newborn babies still receive no anaesthetic.[5,13] In 1987, this practice must be unacceptable in all but the most life-threatening situations, since there is overwhelming evidence that babies can feel pain. The practice of "awake intubations", while still commonly done, must also be questioned, if for no other reason than that the ensuing hypertension may predispose to intracranial haemorrhage.[14] After a paper published in 1981[15] on the use of moderate to high dose fentanyl (30–50 μg/kg) in an air-oxygen mixture, this technique has become more popular in the USA.[16-18] This approach to anaesthetising preterm and newborn babies does not seem to have been taken up in the UK. In a survey lately carried out among British paediatric anaesthetists, 80% stated that they believed that newborn infants (within one week of life) were capable of feeling pain, and yet 48% never used narcotic analgesics and a further 41% seldom did so. The incidence of narcotic use in preterm infants is unknown but it is reasonable to assume that these drugs are given even less frequently. Very few anaesthetists used local anaesthetic blocks either.

The usual reason given why many anaesthetists will not use any agent more potent than nitrous oxide is fear of intraoperative cardiovascular depression or postoperative ventilatory depression. When infants come to surgery dehydrated—eg, after intensive management of heart failure—they are likely to become hypotensive under anaesthesia; in this situation appropriate management with preoperative fluid replacement will reduce the likelihood of this complication[18] Similarly, use of inappropriate concentrations of volatile anaesthetic agents may lead to hypotension It is now known that the MAC of isoflurane[19-20] and halothane[21] is lower in newborn and preterm infants than older infants, and knowledge of MAC values should enable these sick infants to be anaesthetised safely.

The risk of ventilatory depression in these babies is high after any form of anaesthesia [22-23] Many of them will be mechanically ventilated in the postoperative period for respiratory distress syndrome or heart failure. However, if the use of narcotic analgesics or volatile agents necessitates a short period of mechanical ventilation for ventilatory depression, this can be achieved safely. Robinson and Gregory[15] noted in their study that all infants were awake and breathing spontaneously between ventilator breaths within an hour of returning to the nursery

As an alternative for minor surgery, where moderate to high dose narcotics may be inappropriate, local anaesthetic blocks are safe and effective. Several studies have confirmed the effectiveness of spinal anaesthesia for inguinal hernia repair and lower abdominal surgery.[24-25] Most infants undergoing peripheral surgical procedures could be anaesthetised in this way.

It is clear from the publicity surrounding this issue that techniques and attitudes must change. If these sick infants are to be anaesthetised safely, attention must be paid to ensuring that adequate postoperative facilities are available. Medical and nursing staff must be trained to cope with their special needs, which may be different from those of other preterm infants in the neonatal intensive care unit. They may require a period of mechanical ventilation postoperatively, and the appropriate equipment should be available. Many neonatologists and paediatric anaesthetists believe that these infants should be referred to major paediatric centres for surgery. This policy would ensure a more uniform standard of anaesthetic and paediatric care, and enable the financial resources that will inevitably be required to be concentrated in fewer centres. While the current media attention surrounding the emotive issue of infant anaesthesia may be inaccurate and inappropriate, if it results in better care for these vulnerable patients, it may not have been all bad

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POSTNATAL DEVELOPMENT OF THE CUTANEOUS-FLEXOR REFLEX: COMPARATIVE STUDY OF PRETERM INFANTS AND NEWBORN RAT PUPS

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Little is known about somatosensory function and its normal prenatal and postnatal development in human infants. A better understanding is essential in order to assess the consequences of excessive handling and pain-producing procedures undergone by preterm infants needing intensive care. One method of investigating the effect of sensory inputs is to look at the motor reflexes they evoke, although these, of course, also reflect activity in the motor neurons and muscle, as well as in the sensory pathway, and may not necessarily reflect sensory experience. Cutaneous reflexes have been used to establish when connections between the skin and the spinal cord are first made in the fetus (Bradley and Mistretta 1975), but have also been used to study the postnatal maturation of descending motor pathways (Issler and Stephens 1983). The cutaneous flexor reflex has been shown to be particularly well correlated with sensory input (Woolf 1986). This reflex is evoked only by noxious skin stimulation in adults and acts as a defence mechanism whereby the limb is withdrawn from the offending stimulus (Sherrington 1898). It has been shown in adult man to parallel pain perception exactly in terms of threshold, peak intensity and sensitivity to analgesics such as morphine (Janko and Trontelj 1983, Willer 1985).

In the present study we have investigated the flexor reflex in the neonate, with particular reference to the threshold or intensity of skin stimulation required to evoke it and the effect of repeated stimulation. Our aims were to assess the feasibility of using this reflex as a measure of somatic sensation, and to provide comparative data for newborn rat pups and human infants, so that our detailed knowledge of CNS development in the rat can be used to advantage in relation to human development.

Method

Human subjects

The data were obtained from 103 infants of both sexes, 75 of whom were preterm and 28 fullterm. The preterm babies were all patients in the special care baby unit at St. George's Hospital, London, born at 25 to 34·5 weeks postconceptional age (PCA). They were tested at 27·5 to 39·5 weeks PCA. The babies were chosen at random from the unit and were only excluded if they were in a critical state, with severe neurological, cardiovascular or metabolic problems, or were being treated with barbiturates or paralysing agents. In the youngest groups (<27·0 weeks and 27·5 to 29·5 weeks PCA), 14 of 33 thresholds were obtained from babies on ventilators. Inevitably the majority of babies received oxygen therapy during their stay in the unit and 18 per cent had low-grade cerebral haemorrhage from hich they recovered fully. No obvious effects of any of these factors could be found on thresholds, but detailed studies of pathology were not attempted. The fullterm babies were patients in the postnatal ward at St. George's Hospital. They were healthy, normal babies of both sexes, picked at random.

Testing threshold

The threshold testing was performed with the consent of the babies' mothers. Usually the babies were lying in a prone position with their legs slightly flexed, but in a few cases they were lying supine. They were all in a light sleep (*i.e.* stirring) or quietly awake when tested; babies who were deeply asleep or crying and restless were not tested.

The procedure was simply to expose the sole of the foot and briefly establish the threshold for flexion withdrawal of the leg by applying graded von Frey hairs to the lateral plantar surface of the foot. The area used for heel lancing for blood samples was avoided. The threshold response was taken to be a clear withdrawal of the leg, not simply a twitch the toes or flexion of the foot. The evoked flexion reflex was clear, brisk and unequivocal. To test the effect of repeated stimulation on the reflex, the threshold was established and then a von Frey hair of one grade higher intensity was applied to the plantar surface of the foot at five-second intervals for one minute. The effect on the amplitude of the reflex was observed and any change in threshold was measured. Usually the babies were tested only once a day, but on some occasions they were tested two or three times at intervals of several hours. Babies who were in the unit for an extended period were tested at weekly intervals, but the majority (60 per cent) were tested only once. The von Frey hairs were made of nylon monofilaments of graded thicknesses, which, when pressed on the skin, produced forces ranging from 0·003g to 90g. They were sterilized and recalibrated between testing sessions.

Rat pups

Wistar rat pups of both sexes were tested from just after birth to 28 postnatal days (P0 to P28). They were temporarily removed from their litter and placed on their stomach, with the hind-legs slightly flexed and the plantar surface of the feet uppermost. The threshold for the flexion withdrawal reflex to plantar skin stimulation was established with graded von Frey hairs. The foot was then placed with the plantar surface down and the threshold was established on the dorsal surface. As with the human infants, the threshold was taken as that von Frey hair which evoked a brisk, clear and unequivocal withdrawal of the limb.

The effect of repeated stimulation on the reflex was also tested by establishing the threshold and then stimulating the foot at 5- to 10-second intervals for one to two minutes, observing any change in amplitude over this time. The threshold was then tested again and if it had changed the procedure was repeated with the new grade of von Frey hair until there was no further change in threshold.

Results

Cutaneous flexor reflex thresholds

HUMAN INFANTS

Flexion reflex thresholds in newborn infants are very low and gradually increase with PCA. Figure 1 illustrates this rise, and shows that infants of less than 29·5 weeks PCA have thresholds of less than 0·5g, but this gradually increases so that by 37·5+ weeks PCA the threshold at 1·7g is the same as in newborn fullterm infants. This is still a very low-intensity stimulus and is not perceived as noxious in adults. The gradual increase of threshold is not related to postnatal age (PNA) in premature infants but only to PCA. Thus a baby born at 28 weeks and tested four weeks later (32 weeks PCA) will have a similar threshold to a newborn 32-week baby. Figure 2 illustrates that there is no relation between threshold and PNA.

RAT PUPS

Flexion reflex thresholds in newborn rat pups are also very low and increase with PNA. Figure 3 illustrates this for the plantar and dorsal surface of the foot. At birth the thresholds are less than 1·0g and increase over the first two postnatal weeks

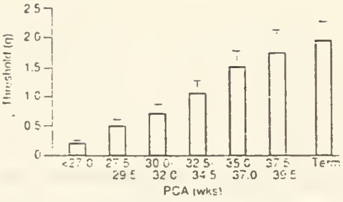

Fig. 1. Increase in threshold of flexor reflex with PCA in preterm and fullterm babies. (N = 6, 27, 34, 31, 32 and 22 for preterm babies; N = 28 for term babies.)

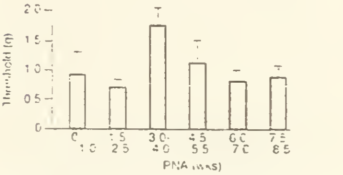

Fig. 2. Lack of relation between flexor reflex threshold and PNA in group of preterm babies born between 25 and 24 weeks PCA (N = 44, 29, 20, 12, 19 and 8.)

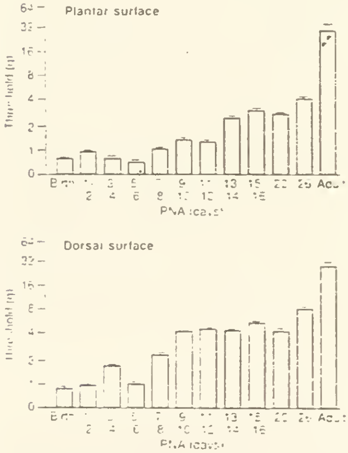

Fig. 3. Increase in threshold of flexor reflex with PNA in newborn rat pups. (10 to 20 animals tested at each age.) Note logarithmic scale of thresholds

to 2·7g on the plantar surface and to 4·7g on the dorsal surface. Much of the increase appears to take place in the second week. Over the third and fourth week the thresholds continue to increase and at 20 to 30g are beginning to approach the high values found in the adult (Woolf 1984).

Sensitization and habituation of the flexor reflex

HUMAN INFANTS

In the youngest infants tested (<27 weeks PCA), repeated stimulation of the plantar skin at five-second intervals resulted in a build-up of the reflex response, such that the amplitute and force of the withdrawal increased and the limb went into rythmic flexor and extensor movements or chronic flexion. The other leg and the trunk also became involved in a mass body movement. This striking build-up or sensitization of the reflex was observed in fewer and fewer infants with increasing PCA. As the incidence of sensitization decreased, habituation of the reflex became a prominent feature. In the oldest infants tested (37·5 to 39·5 weeks PCA), repeated stimulation of the plantar skin resulted in habituation of the response, as is observed in the adult (Dimitrijevic and Nathan 1970). After three to five stimuli no response could be evoked and it was necessary to use stronger stimulation to produce a flexion reflex. Figure 4 illustrates this gradual change from sensitization to habituation of the flexor reflex as PCA increases and shows that the 'change-over' period is at about 32 weeks PCA.

At each age there were also infants whose reflex response did not sensitize or habituate with repeated stimulation, and this was most commonly observed around the 'change-over' period. Each individual baby tested had either a sensitizing or habituating flexor reflex (or no change), but not mixed responses. Figure 5 clarifies this by showing the results of three longitudinal studies in which the effects of repeated stimulation could be tested on the same infants at increasing PCA. It can be seen that there is a clear developmental sequence for the flexor reflex, from sensitization through to no change and finally to habituation, and in two of three cases the 'change-over' was around 32 weeks PCA.

RAT PUPS

Repeated cutaneous stimulation of the foot also resulted in sensitization of the flexor reflex in rat pups. As in human infants, repeated von Frey hair stimulation at five-second intervals caused a build-up of the reflex response amplitude, with rythmic flexor and extensor movements or chronic flexion of the limb, plus involvement of the trunk and other limbs. It was also possible to demonstrate a drop in the reflex threshold. The final threshold, after repeated stimulation at progresively lower intensities, was less than a third of the original value (Fig. 6). This sensitization was particularly prominent in the first postnatal week, and although still present in the second and third weeks, was less pronounced (Fig. 6). By the fourth week repeated stimulation produced habituation, as in the adult (Woolf 1983), such that after three to five stimuli the response failed and progressively higher intensities were required to evoke it.

Discussion

The results show that the threshold for the flexor reflex in newborn infants is very low but increases gradually with age. The threshold depends on PCA rather than PNA and the steady increase appears to occur equally *in utero* or *ex utero*. By 40 weeks PCA the thresholds of preterm babies were equivalent to those of normal fullterm babies. It is unlikely therefore that the low thresholds are a product of preterm birth itself, but rather are a natural feature of the developing reflex. This is supported by the fact that the same developmental sequence was observed in newborn rat pups. Rats also have very low flexor reflex theshold at birth, which gradually increase over the postnatal period. The thresholds of 75 to 100g observed in adult rats (Woolf 1984) are not approached until the fourth postnatal week. In adult man the threshold for noxious sensation with the same von Frey hairs is 30 to 75g and a threshold of 30g has been found for the flexor reflex in a paraplegic patient (Fitzgerald and Shaw, unpublished results). At 40 weeks PCA or

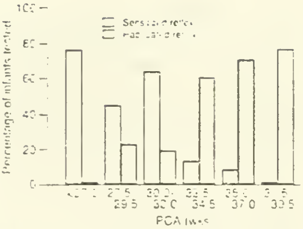

Fig. 4. Sensitization and habituation of flexor reflex in preterm human infants on repeated stimulation of plantar surface of foot at five-second intervals (N = 4, 9, 16, 15, 13 and 6.)

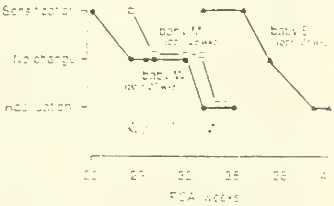

Fig. 5. Longitudinal studies of three individual preterm babies for whom effects of repeated plantar skin stimulation on flexor reflex has been followed over six to nine weeks.

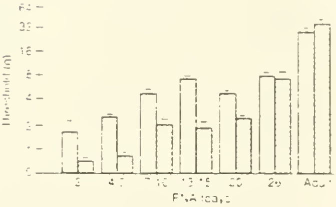

Fig. 6. Sensitization and habituation of flexor reflex in rat pups following repeated stimulation of dorsal surface of hind-paw at five-second intervals. Results are expressed in terms of initial threshold at each PNA (open columns) and final threshold (hatched columns) after a series of repeated stimuli. (Five rats tested at each age.) Note logarithmic scale of thresholds.

term, the threshold was still less than 2g and we do not know whether it continues to rise gradually during childhood or whether there is a more sudden increase to adult levels in the postnatal period.

Exaggerated reflexes in newborn infants (Issler and Stephens 1983, Myklebust *et al.* 1986), kittens (Ekholm 1967) and rat pups (Stelzner 1971, Fitzgerald and Gibson 1984) have been reported, along with marked synchronization of the EMG. Early studies reported that newborn kittens were 'far more responsive to excitations of the skin than adults' (Weed 1917) and 'very irritable to tactile stimuli' (Windle 1929). An important distinction is that in the present study it was the threshold of the reflex rather than its amplitude that was measured and presumably the low thresholds and prominent sensitization observed underlie these augmented responses.

There are several possible reasons for this low cutaneous threshold. Thinner skin could mean that less force is needed to deform the relevant cutaneous nerve-endings in neonates. While this may be a factor, it is certainly not a critical one. Evans and Rutter (1986) have shown that the postnatal influence on skin development is strong and that even the most preterm infant born at 24 weeks PCA has the mature skin of a term infant after two postnatal weeks. Another factor could be the properties of immature cutaneous receptors, but recordings from single cutaneous afferents in newborn and fetal rats have shown that receptive field size and thresholds are the same as in the adult (Fitzgerald 1978*a*, *b*).

At the other end of the reflex arc, the low thresholds may be a reflection of increased excitability in motor output. Since the same low-threshold reflexes are observed in the newborn rat when recording directly from the flexor motor axons (Fitzgerald and Gibson 1984), the properties of immature muscle and neuromuscular junction cannot be major contributory factors. Newborn rat motor neurons are more excitable than adult ones (Fulton and Walton 1986), yet motor units in awake unrestrained newborn rats are surprisingly inactive (Navarrete and Vrbova 1983). Tonic stretch reflexes also are absent in kitten hind-limb muscles (Skoglund 1960), despite the existence of a mature monosynaptic reflex. The fact that proprioceptive excitation is so weak at a time when cutaneous inputs to the same motor neurons are highly excitatory (Ekholm 1967) argues against a generalized increase in membrane excitability of immature motor neurons as a mechanism for the low flexor reflex thresholds. It seems likely that the properties of cutaneous interneurons within the spinal cord underlie the sensitivity of the flexor reflex in neonates. Like immature motor neurons, they could be more easily excitable, but it is also possible that they are not under the same degree of inhibitory control as in the adult (Ekholm 1967). There is now anatomical and physiological evidence to support this (Bicknell and Beal 1984, Fitzgerald 1985, Fitzgerald and Koltzenberg 1986). The slow development of descending inhibitory connections from brain to spinal cord may also account for the sensitization of the flexor reflex in immature rats and humans. Neonatal flexor motor neurons appear to receive both low- and high-threshold afferent input, and perhaps the former is subsequently inhibited to produce the adult pattern. Although adult flexor motor neurons are only excited by noxious skin stimulation, electrical stimulation of cutaneous nerves show them to have Ab as well as Ad and C fibre inputs (Woolf and Swett 1984).

The flexor reflex certainly appears to be a useful measure of somatosensory function in neonates, but since it can be activated by low-threshold inputs and lacks inhibitory control, it is not an exclusive measure of nociceptive function, as it is in the adult. This may be indicative of the general failure to find behavioural and physiological responses that specifically correlate with noxious stimulation in neonates (Owens 1984).

Low reflex thresholds and sensitization may have important implications for the management of preterm infants. Repeated handling will result in excessive excitation of central neurons, which could well affect their function, as well as contribute to uncontrolled changes in blood pressure.

Finally, the data indicate that human reflex development during the final trimester of pregnancy is comparable to the first few postnatal weeks in the rat. This is not surprising in view of the immaturity of the rat CNS at the time of birth. This gives us a valuable timetable for the interpretation of more detailed neurophysiological and neuroanatomical studies.

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SUMMARY

Cutaneous flexor reflex thresholds have been used as a measure of somatosensory function: the authors measured threshold in preterm infants and newborn rat pups. Preterm infants of less than 30 weeks postconceptional age (PCA) had very low thresholds of less than 1·0g, but by 37·5+ weeks PCA thresholds were equivalent to those in normal term babies, although these are still well below adult levels. Newborn rat pups also have very low flexor reflex thresholds, which do not approach adult levels until four postnatal weeks. Repeated stimulation of the foot in preterm babies resulted in sensitization of the flexion reflex up to about 32 weeks PCA. After that age repeated stimulation resulted in habituation, as is observed in the adult. Sensitization also occurred in newborn rat pups, which changed at four postnatal weeks to habituation. The results demonstrate the sensitivity of spinal reflexes to cutaneous inputs in the neonate and it is argued that this results from lack of inhibitory control in the immature spinal cord.

RÉSUMÉ

Développement post-natal du réflexe cutané en flexion: etude comparative du premature et du raton nouveau-ne

Les seuils de réflexe cutané en flexion de nourrissons prematurés et à terme ainsi que de ratons nouveau-nes ont eté enregistrés comme mesure de la fonction somato-sensorielle. Les prematures de moins de trois semaines d'âge conceptionnel (PCA) avaient des seuils tres bas de moins de 1·0g, mais à 37·5 semaines les seuils etaient equivalents de ceux de nourrissons normaux a terme quoique bien en dessous des niveaux adultes. Les ratons nouveau-nés avaient aussi des seuils tres bas qui n'approchaient les niveaux adultes qu'apres quatre semaines post-natales. La stimulation repetee du pied des prematures provoquaient une sensibilisation du réflexe de flexion jusqu'aux environs de 32 semaines PCA apres quoi il y avait habituation. La sensibilisation survenait egalement chez les ratons nouveau-nes mais l'habituation survenait a quatre semaines post-natales. Ces resultats demontrent la sensibilite des réflexes spinaux a la stimulation cutanee chez les nouveau-nes, resultat de manque de contrôle inhibiteur d'une moelle epiniere immature.

ZUSAMMENFASSUNG

Postnatale Entwicklung des kutanen Beugereflexes: Vergleichsstudie zwischen fruhgeborenen Kindern und neugeborenen Ratten

Bei Fruhgeborenen und reif geborenen Kindern und bei neugeborenen Ratten wurde die Reizschwelle des kutanen Beugereflexes als Maß somatosensorischer Funktion getestet. Fruhgeborene mit einem Konzeptionsalter von weniger als 30 Wochen hatten sehr niedrige Reizschwellen von weniger als 1·0g, aber mit 37,5 Wochen waren die Reizschwellen wie bei normalen reifen Neugeborenen, auch wenn diese noch weit unter den Erwachsenenwerten liegen. Die neugeborenen Ratten hatten ebenfalls sehr niedrige Reizschwellen, die die Erwachsenenwerte erst vier Wochen nach der Geburt erreichten. Wiederholte Fußstimulation Fruhgeborener resultierte in einer Sensibilisierung des Beugereflexes etwa bis zum Konzeptionsalter von 32 Wochen, danach kam es zur Gewohnung. Eine Sensibilisierung trat auch bei neugeborenen Ratten auf, aber bei ihnen kam es vier Wochen nach der Geburt zur Gewohnung. Die Ergebnisse zeigen die Empfindlichkeit spinaler Reflexe auf kutane Stimulation bei Neugeborenen, die durch das Fehlen einer inhibitorischen Kontrolle im unreifen Ruckenmark bedingt ist.

RESUMEN

Desarrollo postnatal del reflejo cutaneo flexor: estudio comparativo en lactantes pretermino y en ratas recien nacidas

Se examinaron los dinteles del reflejo cutaneo flexor en lactantes pretérmino y a termino y en ratas recien nacidas, como medicion de la funcion somatosensorial. Los lactantes pretermino de menos de 30 semanas posconcepcion (edad posconcepcion = EPC) tenian unos dinteles muy bajos, de menos de 1·0g, pero a las 37·5 semanas los dinteles eran eqivalentes a los lactantes a termino normales, aun que estos aun estan muy por debajo de los niveles del adulto. Las ratas recien nacidas tambien tenian unos niveles muy bajos que no se acercaban a los de los adultos hasta la cuarta semana postnatal. La estimulacion repetida del pie en niños pretermino dio lugar a una sensibilizacion del reflejo cutaneo flexor hacia las 32 semanas de EPC, despues de lo cual hubo habituacion. La

sensibilizacion tambien se daba en las ratas recien nacidas, pero se habituaron a la cuarta semana postnatal. Estos resultados demuestran la sensibilidad de los reflejos espinales por estimulacion cutanea en recien nacidos, lo que es debido a una falta del control inhibitorio de la medula inmadura.

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MATURATION OF THE NEONATAL SOMATOSENSORY EVOKED RESPONSE IN PRETERM INFANTS

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While considerable interest has been shown in the neonatal visual evoked responses (*e.g.* Gambi *et al.* 1980, Mushin *et al.* 1984, Chin *et al.* 1985, Ellingson 1986) and auditory brainstem evoked responses (*e.g.* Despland and Galambos 1980, Cox *et al.* 1981, Fawer and Dubowitz 1982) of preterm infants, there are no recent reports concerning the maturation of the somatosensory evoked response (SER).

The somatosensory pathway is relatively long compared to the visual and auditory pathways and traverses areas commonly affected by haemorrhagic and/or ischaemic lesions in the neonatal brain. In addition, the pre- and post-central cortical gyri are intimately connected functionally (Penfield and Jasper 1954). The SER may prove of value in the neurological assessment of preterm infants at high risk for later neurological handicaps, but in order to explore this, normal maturational data must be collected.

The purpose of this study, therefore, was to establish normal ranges for the short latency 'N_1' component of the SER in a group of preterm infants during the neonatal period. This component was chosen because of its reproducibility and because it signals the arrival of the afferent impulse at the cerebral cortex (Desmedt *et al.* 1976).

Material and method

The study group consisted of 102 infants born between November 1984 and October 1985 who underwent evoked response testing after informed parental consent had been obtained. 94 of the infants were admitted to the Regional Neonatal Intensive Care Unit at the Liverpool Maternity Hospital, the most common indications for admission being very-low birthweight (VLBW) and problems associated with preterm birth. The remaining eight fullterm infants had a normal delivery and were admitted to postnatal wards.

The median gestational age at birth of the group was 32·0 weeks (range 26·7 to 40·4 weeks) and the median post-menstural age at first test was 33·9 weeks (range 27·7 to 41·4 weeks). The median Apgar score at one minute was 7 (range 2 to 10) and at five minutes was 9 (range 6 to 10). 37 per cent of the infants required intubation for resuscitation at birth and 45 per cent required mechanical ventilatory support for a median of three days (range one to 16 days). Headbox oxygen was used subsequently for a median of two days (range one to 9 days). The maximum inspired oxygen concentration needed during ventilation (or in a headbox) ranged from 25 to 100 per cent, with a median of 50 per cent. All babies were tested when in a stable clinical condition,

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without ventilator or oxygen requirement.

Criteria for inclusion in the study were: (1) no major congenital malformations; (2) no neurological abnormalities or neonatal convulsions; and (3) cranial ultrasound appearances normal throughout admission. According to the neurological follow-up study of all VLBW infant admissions to the Liverpool Maternity Hospital (Cooke 1985), more than 95 per cent of this group would be expected to have a normal outcome.

Infants were tested during natural sleep in their incubators or cots. Sleep stage was not monitored, since the peak latency of the early N_1 component of the SER varies little between active and quiet sleep (Desmedt and Manil 1970). Environmental temperature was kept at a constant level and body temperature was normal before and after testing.

A Medelec MS91a one-channel evoked potential system was used. 0·9cm diameter silver/silver chloride surface EEG electrodes were used for stimulation and recording and interelectrode resistances were measured using an impedance meter (Specialised Laboratory Equipment Model EIT).

Method

The skin was cleaned with methylated spirit and the surface electrodes were attached using double-sided adhesive discs, an additional piece of Blenderm surgical tape being used to prevent electrode displacement. Camjel conductive jelly was injected into the electrodes and the skin was gently scarified with a blunted needle. In this way electrode impedances were kept below 3k/Ohm and this was checked regularly throughout the recording session.

The stimulating electrodes were placed longitudinally along the median nerve at the wrist, at distances of approximately 1cm. The cathode was placed proximally. Square-wave electrical pulses of 0·1 milliseconds (ms) duration were applied at a frequency of one stimulus every two seconds. Intensity of the stimulus was gradually increased until motor threshold was just exceeded (usually between 30 and 90 volts). This intensity was found to be most suitable for optimal SER recording by Ellingson and Ellis (1970). Either median nerve was stimulated, since in setting up the present study to determine optimal stimulating and recording conditions, no asymmetry had been found in the 10 infants studied for this purpose. This is in agreement with the findings of Laget and colleagues (1976), who comment that under standard stimulating and recording conditions the SER is symmetrical from birth.

The peripheral nerve conduction velocity (PNCV) was calculated, using the recording from an electrode placed at Erb's point in the mid-clavicular line, referenced to a mid-frontal electrode, and using an electrode on the upper arm as ground. A sharp negative deflection on the trace signalled the arrival of the afferent volley at the brachial plexus. The amplifier sensitivity was set at 20 microvolts per division (μV/div), the preset filter on the MS91a at 'SCV' (20Hz to 2k/Hz) and the screen width 20ms. Measuring the length of the arm between the stimulating and recording electrodes then allowed the PNCV to be calculated. 50 responses were averaged twice for each PNCV recording and repeated if necessary.

For the cortical SER the electrodes were positioned according to the Picton (1978) modification of the 10-20 electrode system, based on percentage distances from four standard points on the head; the nasion, inion, left and right preauricular points. The active electrodes were positioned at PC_3 and PC_4 and referenced to the mid-frontal position. The site of maximal response (*i.e.* the contralateral parietal hand focus) has been determined by Manil *et al.* (1967) and in the fullterm infant is 50 to 75mm from the midline and 20mm behind the biauricular frontal plane, the measurements in the preterm infant being correspondingly smaller. Sensitivity was set at 20μV/div (or 10μV/div if necessary), the preset filter on the MS91a at 'CER' (2Hz to 100Hz) and the screen width initially at 100ms. Although Desmedt and colleagues (1974) suggested a considerably higher upper limit for the filter in their study of eight normal males, the upper limit of 100Hz was calculated to be satisfactory in this study since the

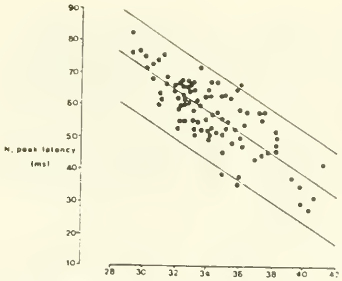

Fig. 1. Graph of N, peak latency of SER against postmenstrual age.

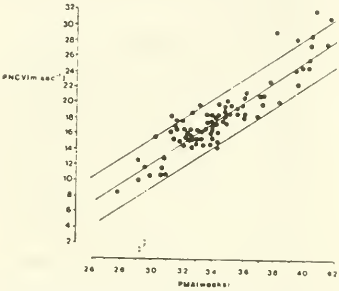

Fig. 2. Graph of peripheral nerve conduction velocity against postmenstrual age.

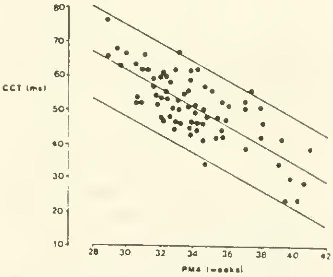

Fig. 3. Graph of central conduction time (CCT) against postmenstrual age.

duration of the N_1 component of the preterm response is very much longer than that of the adult response. In addition, there is no evidence of any systematic distortion of the latency occurring with development within the gestational age-group used in this study, as can be seen from Figure 1. 100 responses were averaged twice and the peak latency of the first prominent negative wave, N_1, was measured using the electronic cursors on the MS91a. If necessary the procedure was repeated.

In order to assess the reliability of the evoked response in relation to the sensory stimulus, the following steps were taken: (1) for each test the two sets of averages were added and subtracted, the response being absent on the subtraction; and (2) a series of responses was recorded in the absence of stimulus presentation, in which case the response was also found to be absent.

The response was easily reproducible if the recording session had to be interrupted for any reason, most commonly to feed and change the baby. During this period, which could last for an hour or two, it was not uncommon for electrodes to become dislodged. Re-application of the electrodes before continuing the recording session did not adversely affect the reproducibility of the response, provided the electrode impedances were below 3k/ohm.

Each recording took about two hours to complete, the clinical status of the infant being monitored throughout.

The statistical package for the Social Sciences—Extended (SPSS-X) was used and regression statistics were calculated using the REGRESSION procedure and multivariate analysis of variance (MANOVA). 95 per cent tolerance limits were estimated from the residual variance values obtained using MANOVA.

Results

Successful recordings, in which clearly identifiable peaks were seen, were obtained in 89·2 per cent of PNVC recordings and 90·2 per cent of SER recordings. Only the results of the first test responses (*i.e.* those tests carried out as soon as possible after birth) were included in the statistical analysis.

Figure 2 shows the relationship found between the PNCV and postmenstrual age (PMA). PMA is the gestational age at birth plus the chronological age at first test. It can be seen that the relationship is linear, with a regression correlation coefficient of $+0\cdot90$ and a two-tailed significance value of $p<0\cdot00001$. The regression equation describing the relationship is:

$$\text{PNVC} = 1\cdot28\ \text{PMA}\ - 26\cdot1$$

Plotting PMA on the vertical axis and PNCV on the horizontal allows PMA to be calculated from the PNCV, as described by Moosa and Dubowitz (1972), with a 95 per cent tolerance limit of 2·19 weeks.

For the two infants tested at less than 29 weeks, the cortical SER consisted of a slow negative wave of long latency, as described by Hrbek *et al.* (1973). After 29 weeks the distinct negative wave, N_1, could be identified within the first 100ms following stimulus presentation. The latency of the N_1 peak was found to decrease linearly with PMA, the regression correlation coefficient being $-0\cdot77$, with a two-tailed significance value of $p<0\cdot00001$ (see Fig. 1). The regression equation is:

$$\text{SER}\ (N_1) = 162\ - 3\cdot05\ \text{PMA}$$

The estimated 95 per cent tolerance limits are shown in the Figure.

Nineteen infants underwent repeat SER testing a week or more after the first recording, and two infants were tested on three occasions. The maturation of response for these infants followed the same course as that for infants tested for the first time at a corresponding PMA. This pattern was seen both in infants who had required mechanical ventilatory support for hyaline membrane disease and in those who had not. Although longitudinal data in this study are available for only a small proportion of the infants tested, it appears that maturation of the SER occurs at the same rate both *in-* and *ex-utero* in infants who have no evidence of neurological damage.

By plotting PMA on the vertical axis and N_1 peak latency on the horizontal, PMA can be predicted from SER, the 95 per cent tolerance limit in this case being 3·34 weeks.

The decrease in N_1 peak latency with PMA is not simply due to increasing PNCV with PMA. The difference in latency between that of the N_1 peak and the Erb's point potential gives an indication of the central conduction time (although a small part of the peripheral pathway between Erb's point and the spinal cord is also included). The calculated regression equation for this central conduction time (CCT) is:

$$\text{CCT} = 144\cdot76\ - 2\cdot76\ \text{PMA}$$

The regression correlation coefficient is $-0\cdot76$, with a two-tailed significance value of $p<0\cdot00001$.

Figure 3 shows the relationship between CCT and PMA and the estimated 95 per cent tolerance limits.

Figure 4 shows two typical responses obtained from preterm infants at 31 and 37 weeks PMA.

Follow-up information has been collected for 95 of the infants in the study. For the other seven, no replies were received from the health professionals contacted by letter about the follow-up of the infants under their care. In 61 cases information was obtained from the regional centre, where the Denver Developmental Screening Test and neurological, hearing and vision testing was carried out. For another 21 infants, who lived further from the regional centre, neurodevelopmental information was obtained from the paediatric consultant at the district general hospital from which the infants had been referred. Four infants did not attend hospital for testing and information was obtained from their general practitioners. The remaining nine were fullterm infants who did not require admission to the neonatal intensive care unit: they underwent routine developmental assessments by clinical medical officers and health visitors, from whom information was obtained.

Since follow-up information was to be obtained from a variety of sources, a simply and clearly structured questionnaire was used to collect the data. The median age at follow-up was 12 months (range six to 18 months).

No infant at the time of testing was found to have delayed development or neurological abnormality, apart from one baby with sensorineural deafness. The

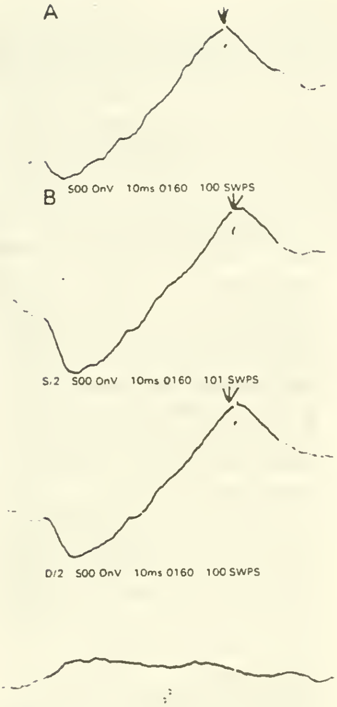

Fig. 4a. SER response from infant of 31 weeks postmenstrual age. N_1 is arrowed (70ms). Top trace: *average A;* second trace: *average B;* third trace: *sum* = $\frac{A+B}{2}$; bottom trace: *difference* = $\frac{A+B}{2}$.

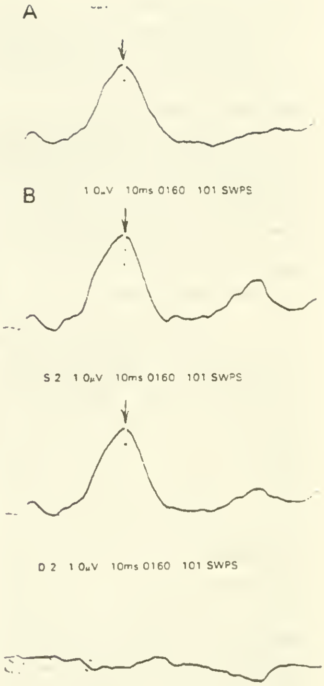

Fig. 4b. SER response from infant of 37 weeks postmenstrual age N_1 peak is arrowed (39ms). Trace details as in Fig. 4a.

period of follow-up is not long enough for definite conclusions to be made about outcome, but as yet there is no evidence to suggest that infants with neurological abnormalities were included in the collection of this normative data.

Discussion

The SER is mediated largely by the dorsal-column medial leminiscal thalamocortical system. The Erb's point potential reflects the mixed nerve action potential as it passes beneath the electrode placed in this position, close to the brachial plexus. This potential is abolished by peripheral-nerve damage distal to the dorsal-root ganglia. The presence of the potential ensures that adequate somatosensory stimulation has been applied to the peripheral nerve. This study demonstrates, as have previous studies on smaller groups of infants, that PNCV increases in a linear manner with increasing PMA (*e.g.* Dubowitz *et al.* 1968).

The N_1 peak latency of the cortical response was found to decrease linearly with PMA. This change reflects maturation of the central pathway and not merely maturation of the peripheral nerves. Normal ranges with 95 per cent tolerance limits have been estimated.

The precise locations of the neural generators of the central SER have not been conclusively pin-pointed, but it has been suggested that the distribution of the early SER components can be explained by the existence of two separate generators in the post-central gyrus, one situated in the posterior wall of the central sulcus and the other in the anterior portion of the crown of the post-central gyrus, near the central sulcus. This agrees with the observed distribution of N_1 and a frontal positivity of similar latency (Allison *et al.* 1980).

From a practical clinical viewpoint, the early N_1 component signals the arrival of the neural impulse at a cortical level, and normal peak latency implies that the somatosensory pathway is intact to this level. The response is reproducible, less variable than the longer latency components and relatively unaffected by sleep state. Using an electrical stimulus at a suitably slow rate allows 90 per cent successful recording. Other authors have used alternative stimuli (Pratt *et al.* 1981) and faster rates of stimulus presentation (Willis *et al.* 1984), but with lower success rates in newborn infants. Thus several factors make the N_1 component of the SER simple to evaluate quantitatively. The complete procedure requires only four appropriately sited recording electrodes and two stimulating electrodes for unilateral recording.

Recordings from lower-limb nerves could not be undertaken in this study in addition to the measurement of median-nerve responses, since recording sessions would have become unacceptably long using a single-channel recorder, although such recordings would be of interest in diplegia among very low-birthweight infants. However, in the study by Laget and colleagues (1976), a child with lower-limb monoplegia was found to have abnormal SER to median-nerve stimulation on the corresponding side. Also, an infant we have studied who had bilaterally abnormal SERs in the neonatal period has lower-limb dystonia at the age of one year.

The central component of the SER is of considerable interest in the preterm infant who is susceptible to neonatal cerebral haemorrhage and ischaemia, and subsequently is at risk for developing neurological handicap. The sensory and motor pathways lie in close proximity in regions of the brain likely to be affected by haemorrhagic and ischaemic lesions; in addition, the sensory and motor cortices are intimately connected, as previously mentioned. Thus lesions affecting motor pathways are likely also to affect the sensory pathways and the SER.

Preliminary results of an investigation of a small group of infants with cranial-ultrasound or neurological abnormalities in the neonatal period has shown normal PNCV values in each case, but abnormal cortical SER recordings (see pp. 215–221).

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SUMMARY

A group of 102 neurologically normal neonates with gestations between 26 and 40 weeks, without abnormality on cranial ultrasound, underwent evoked response testing. Satisfactory results were obtained for 90 per cent of the infants. Normal ranges with 95 per cent tolerance limits for the short-latency N_1 component of the response were obtained at postmenstrual ages between 29 weeks and term. Somatosensory evoked responses are a practical tool for evaluating sensorimotor pathways in the newborn infant's brain.

RÉSUMÉ

Maturation des potentiels évoqués somato-sensoriels neo-nataux chez les prématures

Une recherche de potentiels évoqués a été effectuée sur un groupe de 102 nouveaux-nés sans anomalie a l'echographie cranienne, apres une grossesse de 26 a 40 semaines. Des resultats satisfaisants ont éte obtenus pour 90 pour cent des nourrissons. Des resultats contenus dans les limites de tolerance à 95 pour cent ont ete obtenus pour la composante N_1 à breve latence de la réponse, aux âges postmenstruels compris entre 29 semaines et le terme. Les potentiels evoques somato-sensoriels constituent un outil pratique d'évaluation des voies sensorimotrices du cerveau du nouveau-né.

ZUSAMMENFASSUNG

Reifung neonataler somatosensorisch evozierter Potentiale bei Fruhgeborenen

Bei einer Gruppe von 102 neurologisch unauffalligen Neugeborenen mit einem Gestationsalter zwischen 26 und 40 Wochen, bei denen im Ultraschallbild des Schädels keine abnormen Befunde nachweisbar waren, wurden die evozierten Potentiale untersucht. 90 Prozent der Kinder hatten zufriedenstellende Ergebnisse. Normalwerte mit 95 Prozent Toleranzgrenze fur N_1 wurden zwischen 29 und 40 Wochen (postmenstruelles Alter) gefunden. Somatosensorisch evozierte Potentiale eignen sich gut zur Beurteilung sensomotorischer Bahnen im Gehirn neugeborener Kinder.

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SHORT-LATENCY CORTICAL SOMATOSENSORY EVOKED RESPONSES OF PRETERM INFANTS WITH ULTRASOUND ABNORMALITY OF THE BRAIN

Valerie J. Klimach
Richard W. I. Cooke

Cranial ultrasound scanning through the anterior fontanelle has provided a major advance in the detection of neonatal haemorrhagic and ischaemic brain-injury and post-haemorrhagic hydrocephalus (Levene 1981, Levene *et al.* 1981, Lipscomb *et al.* 1983). An anatomical diagnosis is made in this way, but evoked responses can give insight into the functional integrity of neural pathways following cerebral injury in the newborn and may prove useful in their assessment.

This study was designed to determine, first, whether infants with ultrasound diagnoses of abnormality of the brain during the neonatal period have cortical somatosensory evoked responses (SERs) which differ from age-matched controls; and second, by follow-up, to determine whether SER abnormalities in the neonatal period have predictive value for later neurological handicap.

Material and method

Normal ranges for the N_1 peak latency were obtained using the SER recordings from 102 neurologically normal neonates between 27·7 and 41·4 weeks post-menstrual age (PMA) (see pp. 208-214). PMA is the gestational age at birth plus chronological age at time of first SER recording.

SERs were then recorded from 30 infants with abnormalities on cranial ultrasound examination, eight of whom had also suffered convulsions during the neonatal period. Their mean gestational age at birth was 30·5 weeks (range 24·7 to 40·0 weeks) and their mean PMA at first test was 35·3 weeks (range 29·6 to 44 weeks). All the infants were in a stable clinical condition, without ventilator support or oxygen requirement, when first tested.

The babies could be broadly divided into five groups according to their ultrasound findings (Table I).

The equipment used and procedure followed have been described in our previous paper.

Since lesions were frequently asymmetrical on ultrasound scanning, bilateral cortical SERs were recorded, both median nerves being stimulated sequentially. Peripheral nerve conduction velocity (PNCV) was measured bilaterally before recording from the scalp overlying the corresponding parietal projection area.

The latency of the first negative peak of the cortical response was measured and designated N_1, although in a grossly abnormal response the first negative peak may not correspond to the N_1 component seen in the normal SER. If no distinct and reproducible negative peak was seen within the first 100ms of stimulus

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adipocytes.[18] The other results establish that the serum of the patient contained antibodies to the insulin receptor. It seems reasonable to conclude that the patient's hypoglycaemia was due to the presence of these antibodies. Most previous cases of insulin-receptor antibodies, although the antibodies had insulin-like effects in vitro, have been characterised by hyperglycaemia and severe insulin resistance in vivo. The reason for the difference between previous cases and our patient remains to be established. In vitro, autoantibodies to the insulin receptor may reduce the number of insulin receptors on cultured cells,[7] so that insulin resistance might be expected to develop as the titre of antibodies rises. However, there is no evidence that the reported patients with insulin resistance had passed through a phase of fasting hypoglycaemia.

We have been unable to prove conclusively that there is a direct link between Hodgkin's disease and the appearance of the anti-receptor antibodies in this patient. However, such a link is suggested by the previous development of an autoimmune haemolytic anaemia, which was overcome by treatment of the Hodgkin's disease, and by the lymphocyte-predominant nature of the tumour. It has been suggested that the latter variety of Hodgkin's disease is a tumour of B lymphocytes, with the implication that autoantibodies could be produced by a single clone of cells. Exploration of this possibility by means of gene probes did not reveal evidence of a monoclonal rearrangement of DNA.

We can only speculate on the stimulus giving rise to the formation of the receptor antibody. Since insulin receptors are very widely distributed, the expression of an abnormal receptor by the tumour cells is one possibility; another is the expression of insulin-receptor antibodies as an anti-idiotype response to insulin-antibody complexes.[19] The lack of evidence for insulin antibodies and the normal plasma insulin levels appear to exclude this possibility.

Hypoglycaemia appears rare in Hodgkin's lymphoma[20] but our patient is not unique (see Braund and colleagues' paper, p 237 of this issue). Certainly, the possibility that hypoglycaemia may be due to insulin-receptor autoantibodies should be considered in all cases of fasting hypoglycaemia for which a cause cannot readily be found. When the underlying cause cannot be treated steroids may alleviate the symptoms through their effect on antibody formation.[8]

We thank Dr B. T. Hale for permission to include details of his patient, Dr N. Rooney for the DNA studies, and Dr G. S. G. Spencer of the AFRC Institute of Food Research, Langford, for the somatomedin assay. The studies were supported by grants from the Bristol and Weston Health Authority and the British Diabetic Association.

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When the following paper by Dr Anand and his colleagues appeared in our issue of Jan 10 we failed to include the five figures referred to in the text. With our renewed apologies to the authors, we now reproduce the complete paper.

RANDOMISED TRIAL OF FENTANYL ANAESTHESIA IN PRETERM BABIES UNDERGOING SURGERY: EFFECTS ON THE STRESS RESPONSE

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Summary In a randomised controlled trial, preterm babies undergoing ligation of a patent ductus arteriosus were given nitrous oxide and d-tubocurarine, with (n = 8) or without (n = 8) the addition of fentanyl (10 µg/kg intravenously) to the anaesthetic regimen. Major hormonal responses to surgery, as indicated by changes in plasma adrenaline, noradrenaline, glucagon, aldosterone, corticosterone, 11-deoxycorticosterone, and 11-deoxycortisol levels, in the insulin/glucagon molar ratio, and in blood glucose, lactate, and pyruvate concentrations were significantly greater in the non-fentanyl than in the fentanyl group. The urinary 3-methylhistidine/creatinine ratios were significantly greater in the non-fentanyl group on the second and third postoperative days. Compared with the fentanyl group, the non-fentanyl group had circulatory and metabolic complications postoperatively. The findings indicate that preterm babies mount a substantial stress response to surgery under anaesthesia with nitrous oxide

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and curare and that prevention of this response by fentanyl anaesthesia may be associated with an improved postoperative outcome.

Introduction

THE marked changes in circulating concentrations of hormonal and metabolic variables found in preterm babies during and after surgery indicate that catabolism and substrate mobilisation occur during the perioperative period. Also, surgical stress responses last longer in preterm than in full-term babies[1,2] and are greater in magnitude than those of adult patients.[3] Preterm neonates may be ill-equipped to meet the metabolic demands of a severe and prolonged catabolic reaction to surgery because of their precarious metabolic balance during adaptation to the post-natal environment and nutrition.[4] They have limited body reserves of fat, protein, and carbohydrate and have to meet the metabolic cost of rapid growth and organ maturation. In view of their physiological and metabolic immaturity, it is not surprising that postoperative morbidity and mortality is high in preterm babies.[5]

An analysis of 40 published reports has shown that 77% newborn babies undergoing surgical ligation of patent ductus arteriosus (PDA) had received muscle relaxants either alone or with nitrous oxide given intermittently.[2] Such clinical practice may have resulted from the traditional beliefs that preterm babies are not able to perceive pain and that they may react adversely to any anaesthetic agent.[2,6] Fentanyl anaesthesia has been shown to be safe and effective.[7-9] We describe here a randomised controlled trial designed to investigate the hypothesis that the surgical stress responses of preterm babies receiving fentanyl anaesthesia are no different from those of newborn babies anaesthetised conventionally with nitrous oxide and curare.

Methods

Approval of the Central Oxford Research Ethics Committee and written parental consent were obtained to study 16 preterm babies undergoing PDA ligation (table I). None of these newborn babies had had haemorrhage, trauma, hypothermia, or hypoxia in the 72 h before surgery. All were being ventilated before surgery; and all underwent a uniform surgical procedure done by the same surgeon. Feeds were withheld for 4–6 h before surgery, and an intravenous dextrose infusion was maintained at 4–6 mg/kg/min throughout the study. Postoperative analgesia consisted of diamorphine (0·1 mg/kg), timed such that it was not injected in the 2 h before blood sampling. Blood (1·0–1·5 ml) was sampled just before the induction of anaesthesia, at the end of surgery, and 6, 12, and 24 h postoperatively. Urine was collected during the second 12 h period of the 3 days following surgery.

Analytical methods.—Blood concentrations of glucose, lactate, pyruvate, acetoacetate, 3-hydroxybutyrate, alanine, and glycerol were measured by specific enzymatic methods;[10] plasma insulin[11] and glucagon[12] by radioimmunoassay techniques, and plasma adrenaline and noradrenaline by double-isotope radioenzymatic assay.[13] The steroid hormones (aldosterone, corticosterone, 11-deoxycorticosterone, progesterone, 17-hydroxyprogesterone, 11-deoxycortisol, cortisol, and cortisone) were isolated by automated 'Sephadex' LH-20 chromatography after extraction and were measured by specific radioimmunoassays.[14] Urine creatinine levels were measured by an autoanalyser using the Jaffe rate colorimetry method, and urinary 3-methylhistidine was measured by an automated fluorimetric method.[15]

Trial design and analysis.—Preterm babies were randomised to two anaesthesia groups, both of which were given nitrous oxide (50%) and curare (0·5 mg/kg), but babies randomised to the fentanyl anaesthesia group also received intravenous fentanyl (10 µg/kg). A schedule for balanced randomisation in blocks was prepared by the National Perinatal Epidemiology Unit, Oxford, and was retained by them until completion of the trial. To test the hypothesis stated above, four index variables were selected (plasma adrenaline, plasma noradrenaline, blood glucose, and the urinary 3-methylhistidine/creatinine ratio) and the standardised difference between groups was calculated on the basis of previous studies and clinical relevance. With this standardised difference, the sample size required to give 80% power to the trial (for $\alpha = p < 0·05$) was calculated from a standard nomogram.[16] The Mann-Whitney U test was used for statistical comparison between the groups and no interim data analyses were done. The "response" of each baby was characterised by the change in each hormonal or metabolic variable from its preoperative value; for purposes of clarity, all data are presented as mean and SEM.

TABLE I—COMPARISON OF PATIENT CHARACTERISTICS AND CLINICAL MANAGEMENT BEFORE AND DURING SURGERY BETWEEN NEWBORN BABIES IN THE FENTANYL AND NON-FENTANYL ANAESTHESIA GROUPS

—	Fentanyl anaesthesia (n = 8)	Non-fentanyl anaesthesia (n = 8)
Gestation (weeks)	28·6 (0·7)	28·3 (0·3)
Birth weight (kg)	1·1 (0·1)	1·0 (0·1)
Age at surgery (days)	13 (1)	17 (3)
Weight at surgery (kg)	1·1 (0·1)	0·9 (0·1)
Pre-op starvation (h)	4·9 (0·4)	4·9 (0·3)
Dextrose infusion rate (mg/kg/min)		
Pre-op (6 h)	4·4 (0·4)	5·0 (0·6)
Intra-op	4·8 (0·4)	5·5 (0·7)
Post-op (24 h)	4·9 (0·4)	5·3 (0·4)
Temperature loss (°C)	0·6 (0·1)	0·8 (0·3)
Dose of d-tubocurarine (mg/kg)	0·56 (0·08)	0·57 (0·10)
Dose of fentanyl (µg/kg)	12·2 (1·5)	–

Results given as mean (SEM).
Differences between groups non-significant (by Mann Whitney U test) for all items.

Results

Hormonal Changes

There were no significant differences between the fentanyl group and non-fentanyl group in any of the plasma hormone concentrations measured before surgery. Plasma adrenaline rose considerably during surgery in the non-fentanyl group but in the fentanyl group it fell during surgery and remained below preoperative values thereafter (fig 1); the differences between the two groups were significant at the end of surgery ($p < 0·002$), and at 6

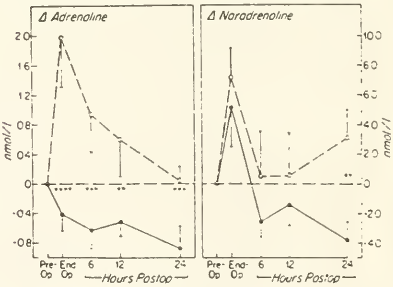

Fig 1—Comparison of changes in plasma adrenaline and plasma noradrenaline concentrations between babies in the fentanyl (—, n = 8) and non-fentanyl (---, n = 8) anaesthesia groups.

All values = mean ± SEM. Mann-Whitney U test: **** $p < 0·002$, *** $p < 0·01$, ** $p < 0·025$.

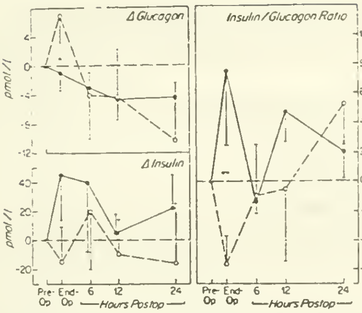

Fig 2—Comparison of changes in plasma insulin and plasma glucagon concentrations and the insulin/glucagon molar ratio between babies in the fentanyl (—, n = 8) and non-fentanyl anaesthesia groups (—, n = 8).

All values = mean ± SEM. Mann-Whitney U test: ** $p<0\cdot025$, * $p<0\cdot05$.

($p<0\cdot01$), 12 ($p<0\cdot025$), and 24 h ($p<0\cdot01$) after surgery. The noradrenaline responses of the two groups were significantly different only at 24 h postoperatively ($p<0\cdot025$) (fig 1). Plasma glucagon concentrations increased during surgery in the non-fentanyl group but were unchanged in the fentanyl group, and the difference between the two groups at the end of surgery was significant ($p<0\cdot05$). Although the two groups did not differ significantly in insulin responses, the insulin/glucagon molar ratio increased during surgery in the fentanyl group and decreased in the non-fentanyl group, the difference at the end of surgery being significant ($p<0\cdot025$) (fig 2).

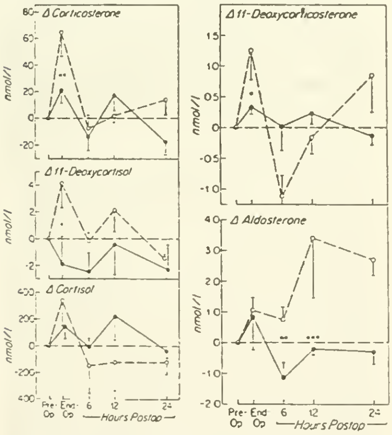

Fig 3—Comparison of changes in the plasma concentrations of glucocorticoid hormones (left) and mineralocorticoid hormones (right) between babies in the fentanyl (—, n = 8) and non-fentanyl (—, n = 8) anaesthesia groups.

All values = mean ± SEM Mann-Whitney U test: *** $p<0\cdot01$, ** $p<0\cdot025$, * $p<0\cdot05$.

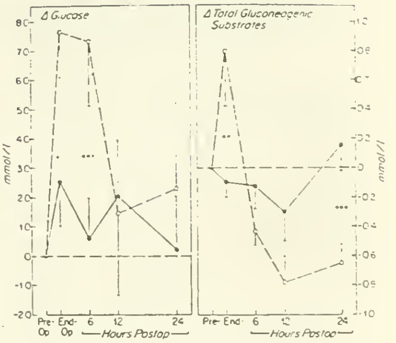

Fig 4—Comparison of changes in the blood concentrations of glucose and total gluconeogenic substrates between babies in the fentanyl (—, n = 8) and non-fentanyl (—, n = 8) anaesthesia groups.

All values = mean ± SEM. Mann-Whitney U test: *** $p<0\cdot005$, ** $p<0\cdot01$, * $p<0\cdot025$.

There were no significant differences between the cortisol responses of the two groups during or after surgery (fig 3). However, corticosterone ($p<0\cdot025$) and 11-deoxycortisol ($p<0\cdot05$) responses during surgery were greater in the non-fentanyl than in the fentanyl babies (fig 3). In the non-fentanyl group, the 11-deoxycorticosterone responses were significantly greater at the end of surgery ($p<0\cdot05$), whereas aldosterone responses were greater at 6 ($p<0\cdot025$) and 12 h ($p<0\cdot01$) postoperatively (fig 3).

Metabolic Changes

The hyperglycaemic response during surgery in the non-fentanyl group was three times greater than that in the fentanyl group ($p<0\cdot025$) and was maintained at 6 h postoperatively ($p<0\cdot005$) (fig 4, table II). Blood lactate and pyruvate concentrations increased during surgery in the non-fentanyl group but remained unchanged in the fentanyl group ($p<0\cdot02$ at the end of operation). At 24 h postoperatively blood lactate and pyruvate values had fallen below preoperative levels in the non-fentanyl group (with significant differences between the two groups) (table II). Similarly, blood levels of total gluconeogenic substrates (sum of the blood concentrations of lactate, pyruvate, alanine, and glycerol) in non-fentanyl babies increased substantially during surgery and fell postoperatively (fig 4), giving rise to significant differences between the groups at the end of surgery ($p<0\cdot01$) and at 24 h postoperatively ($p<0\cdot005$).

Urinary Nitrogenous Constituents

The postoperative changes in the 3-methylhistidine/creatinine molar ratios (3MH/Cr) were measured in urine collected from 7 babies in the fentanyl group and 6 in the non-fentanyl group (fig 5). The urinary 3MH/Cr ratios were similar in the two groups on the first postoperative day, but they were higher in the non-fentanyl than in the fentanyl group on the second ($p<0\cdot05$) and third ($p<0\cdot05$) postoperative days

TABLE II—COMPARISON OF CHANGES IN BLOOD METABOLITE CONCENTRATIONS BETWEEN NEWBORN BABIES IN THE FENTANYL AND NON-FENTANYL ANAESTHESIA GROUPS

	Fentanyl		Mann-Whitney U Test	Non-fentanyl	
Metabolite	n	Mean (SEM)		Mean (SEM)	n
Glucose (mmol/l)					
Pre-operative	8	8·9 (1·1)	NS	8·2 (0·9)	8
Δ Glucose (mmol/l)					
End-op	8	2·6 (1·6)	p < 0·025	7·6 (1·6)	8
6 h post-op	8	0·6 (1·4)	p < 0·005	7·3 (2·3)	8
12 h post-op	7	2·1 (1·9)	NS	1·4 (2·9)	8
24 h post-op	8	0·2 (1·9)	NS	2.3 (3·3)	5
Lactate (mmol/l)					
Pre-operative	8	0·9 (0·4)	NS	1·6 (0·3)	8
Δ Lactate (mmol/l)					
End-op	8	−0·1 (0·1)	p < 0·02	0·7 (0·3)	8
6 h post-op	7	−0·1 (0·1)	NS	−0·4 (0·1)	8
12 h post-op	7	−0·3 (0·2)	NS	−0·7 (0·2)	8
24 h post-op	8	0·1 (0·1)	p < 0·005	−0·6 (0·1)	5
Pyruvate (mmol/l)					
Pre-operative	8	0·12 (0·02)	NS	0·13 (0·01)	8
Δ Pyruvate (mmol/l)					
End-op	8	0·00 (0·01)	p < 0·02	0·05 (0·03)	8
6 h post-op	8	0·00 (0·02)	NS	−0·01 (0·01)	8
12 h post-op	7	−0·02 (0·01)	NS	−0.02 (0·01)	8
24 h post-op	8	0·03 (0·02)	p < 0·01	−0·03 0·01)	5

Δ = change from pre-operative levels.

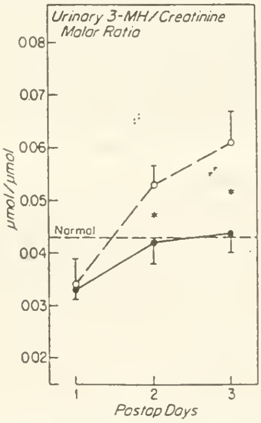

Fig 5—Comparison of urinary 3-methylhistidine/creatinine ratios between babies in the fentanyl (—, n = 7) and non-fentanyl anaesthesia groups (-—, n = 6).

Urine was collected during the second 12-hour-period of each postoperative day, normal value was taken from the study of healthy preterm babies by Ballard et al.[25]

All values = mean ± SEM Mann-Whitney U test: * $p < 0·05$

Clinical Outcome

Babies in the non-fentanyl group were more likely to require an increase in ventilatory support after surgery and to have circulatory or metabolic complications (table III). In addition, 2 babies who had normal cranial ultrasound scans preoperatively developed intraventricular haemorrhages during or soon after surgery. In the fentanyl group a body temperature variability of between 35·8 and 37·7°C was observed during the first 6–8 h after surgery.

TABLE III—CLINICAL COMPLICATIONS DURING THE POSTOPERATIVE PERIOD IN THE FENTANYL AND NON-FENTANYL GROUPS

—	Fentanyl (n = 8	Non-fentanyl (n = 8
Increased ventilation requirements	1	4
Frequent attacks of spontaneous bradycardia	1	4
Hypotension	0	2
Poor peripheral circulation	0	2
Glycosuria	0	1
Metabolic acidosis	0	2
Intraventricular haemorrhage	0	2
Temperature variability	6	0

Discussion

The two groups of preterm babies in this trial were similar in their clinical characteristics and were managed in the same way perioperatively apart from the use of fentanyl anaesthesia in one group. They differed considerably in their hormonal stress responses, particularly in their adrenaline responses. All patients had raised plasma adrenaline and noradrenaline levels before surgery, which may be a reflection of the stress imposed on them by hyaline membrane disease and other clinical factors. A characteristic adrenaline response, similar to that reported previously,[1] was observed in the non-fentanyl group, whereas adrenaline values fell during surgery in all babies given fentanyl and remained below preoperative values thereafter. Similar differences did not occur in the noradrenaline response, either because of the variability in noradrenaline kinetics in plasma or a selective suppression of the adrenomedullary response to surgery.[17] Inhibition of the catecholamine responses to surgery by fentanyl has been reported in adults[18] but, to our knowledge, not in newborn babies.

Plasma glucagon responses in the non-fentanyl group probably resulted from a stimulation of glucagon secretion by the adrenaline release during surgery.[1] Plasma insulin responses in both groups were similar to the pattern of changes reported previously.[1] However, inhibition of insulin secretion in the non-fentanyl group may be inferred from the decrease in the insulin/glucagon ratio, together with the lack of an insulin response to the substantial hyperglycaemia in this group.

The adrenocortical responses of premature babies were characterised by diminished secretion of the final products of steroid biosynthesis and increased secretion of the precursor steroid hormones. Since the hydroxylase enzymes in the fetal adrenal cortex are known to mature from the proximal to the distal end of the steroid biosynthetic pathway,[19] such a pattern may reflect the immaturity of steroid biosynthesis in preterm babies. Thus, it is not surprising that at the end of the operation significant differences were observed between the two groups in the corticosterone and 11-deoxycortisol responses but not in the cortisol responses. Similar differences between the two groups occurred in 11-deoxycorticosterone responses during surgery and the aldosterone responses postoperatively. In adult patients fentanyl anaesthesia produces a similar inhibition of the adrenocortical stress responses,[20] as indicated by its effect on measurement of plasma cortisol concentrations (the precursor steroid hormones were not measured).

The most prominent difference in the metabolic responses of the two groups was the magnitude and duration of the hyperglycaemic response to surgery. We propose that the prevention of massive hyperglycaemia in the fentanyl group was due to their decreased adrenaline, glucocorticoid, and glucagon responses, together with an increase in the insulin/glucagon ratio.

Increases in blood lactate and pyruvate concentrations were observed only in the non-fentanyl group. Arteriovenous catheterisation studies in adults have shown that adrenaline release during surgery may increase lactate and pyruvate production from glycogen breakdown in peripheral tissues.[21] Postoperatively, however, the levels of gluconeogenic substrates decreased below preoperative values in the non-fentanyl group, probably because of the utilisation of these substrates for gluconeogenesis and excessive glucose production. In addition, it is posssible that the limited metabolic stores in preterm babies[4] could not support the production of gluconeogenic substrates for long into the postoperative period. Similar effects of fentanyl have been reported in adult patients undergoing surgery,[3,20] although the doses of fentanyl used were much greater (30–50 µg/kg) than those we gave to preterm babies. This difference may possibly be related to the moderate stress associated with PDA ligation, to the greater sensitivity of newborn infants to opioids,[22] or to the release of endogenous opioids in the newborn.[23]

The most important clinical consequence of a catabolic stress reaction has been said to be that of increased protein breakdown after surgery.[25] In this study, trends of endogenous protein breakdown were investigated by measurement of the urinary 3-MH/Cr ratio during the 3 days following surgery, and greater increases were found in the non-fentanyl group than in the fentanyl group. Although changes in this ratio may not specifically represent skeletal muscle breakdown, several studies in preterm babies[24,25] have shown that raised 3-MH/Cr ratios were associated with catabolism, negative nitrogen balance, weight loss, and a poor clinical condition.

The various complications observed in the non-fentanyl group and their clinically unstable course after surgery formed a clinical pattern that was distinct from that in the babies who received fentanyl anaesthesia. Rapid changes in blood glucose may have detrimental consequences in preterm babies because of their effect on plasma osmolality.[2,26] In 2 babies with marked blood glucose changes during surgery, an intraventricular haemorrhage was noted for the first time in the early postoperative period. However, no causal inferences can be made from this incidental finding.

In view of existing notions on pain perception and management of pain in the human newborn baby further clinical implications arise from the interpretation of these results. Studies in laboratory animals and in adult man show that the stress response to surgery is mediated by neural impulses, including those arising from injury at the site of the operation and acting via the hypothalamus; the response can be abolished either by regional anaesthesia of the relevant area or by suppression of the hypothalamus and cerebral cortex by, for example, opioid analgesia. Since both of these techniques ensure absence of pain during surgery (even though awareness may be intact during epidural anaesthesia, or diminished during opioid analgesia),[3] it follows that pain itself is an important factor in the production of the stress response to surgery. It is widely believed[26,27,28] that, because of lack of myelination in the central nervous system, newborn babies are not capable of perceiving or localising pain and that they may not be capable of interpreting pain since they do not have a memory of previous painful experiences. However, even very premature infants will grimace, vocalise, and withdraw the limb in response to a needle prick. Furthermore, in-vivo measurements of metabolic activity in the neonatal brain[29] have shown that the regions associated with pain perception (the sensorimotor cortex, thalamus, and the midbrain-brainstem region) have the maximum metabolic activity.

None of the infants in this study displayed any clinical evidence of pain during the surgical procedure, but the very substantial stress response observed in those receiving only nitrous oxide and curare could imply that this commonly used anaesthetic regimen did not completely dampen the response to pain. Clearly, the perception, measurement, and management of painful experiences in the premature infant are very important topics for further exploration. We would suggest that the degree of analgesia, particularly in paralysed and ventilated infants, can be assessed reliably only by measurement of the biochemical and endocrine markers of stress.

Whatever the precise mechanism by which the stress response is initiated in preterm babies, our results showed that this response was abolished by low doses of fentanyl, which also improved clinical stability during and after surgery. Other studies have shown that much larger doses of fentanyl (30–50 µg/kg) produce a similar clinical stability in preterm babies undergoing PDA ligation.[7-9]

Our study has confirmed previous observations that preterm neonates mount a substantial stress response to surgery done under conventional anaesthesia. On the basis of pre-selected criteria, this randomised trial has rejected the hypothesis that fentanyl anaesthesia does not alter the hormonal and metabolic stress responses of preterm babies. In addition, it has generated hypotheses suggesting that prevention of the massive stress response of preterm babies may lead to an improvement in their clinical outcome following surgery.

We thank Dr A Wilkinson and Dr A Gunning for permission to study their patients; members of the Nuffield department of anaesthetics and the nursing and clinical staff in the Special Care Baby Unit, John Radcliffe Hospital, Oxford, for their cooperation; Prof S. R. Bloom and Prof M. J Brown for permission to work in their laboratories; and Miss M. Russell for developing the 3-methylhistidine assay.

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ANAESTHESIA AND SURGERY IN CHILDREN

SIR,—Dr Anand and colleagues (Jan 31, p 243) compare hormonal and metabolic responses of babies undergoing ligation of a patent ductus arteriosus under what was, in my opinion, insufficient anaesthesia or under sufficient anaesthesia, in which fentanyl was given with curare and nitrous oxide. The finding of decreased "stress response" under adequate anaesthesia is not really surprising. Surprising, however, is the statement that "none of the infants in this study displayed any clinical evidence of pain during the surgical procedure". Since all the infants were curarised how could they have signalled pain?

Doctors caring for children are often unaware of the fact that a painful stimulus causes a variety of behavioural, emotional, and vegetative reactions in newborn and premature babies. These are easily recognised, even without complex laboratory methods, and they are difficult to interpret in terms other than distress, anger, unease, or, simply, pain. Any experienced nurse or competent mother in Oxford, Kiel, or Newcastle upon Tyne would have been able to describe reliably how babies react to a heel stab or a venepuncture—not to mention thoracotomy—when not paralysed.

At a time of increasing public concern about the well-being of laboratory animals equal rights for babies are still being debated, although conclusive statements on the matter were formulated decades ago. In 1949, Peiper[1] wrote: "The adult reserves for himself the right to be protected against pain during surgical intervention. Because of their sensitivity to pain, newborns and infants have the same right, but contrary to the adult, they are defenceless when their rights are violated. Surgeons, who declare infants insensitive to pain and—as I have witnessed—perform operations for pylorospasm without anaesthesia, do so contrary to everyday experience and scientific knowledge."

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[1] Peiper A. Die Eigenart der kindlichen Hirntätigkeit. Thieme. Leipzig, 1949 (translation cited in. Cerebral function in infancy and childhood, 3rd ed. New York. New York Consultants Bureau, 1963. 539–41).

SIR,—Dr Anand and colleagues refer to "traditional beliefs that preterm babies are not able to perceive pain". This is a wholly unacceptable tenet. In my, albeit limited, experience in this area, it is more the continuation of Anand and colleagues' sentence ("they may react adversely to any anaesthetic agent") that has limited the use of narcotic analgesics in preterm babies. Yet in the study, the patients who did not receive fentanyl required more postoperative ventilation.

Anand and his co-workers have shown that newborn babies mount a profound stress response to surgery if analgesia is withheld. I do not believe that nitrous oxide alone is sufficient analgesia for major surgery.

How can an ethics committee approve a study in which half the patients have analgesia withheld? What is meant by "informed consent" in such circumstances? How many parents were told their children would receive no major analgesia intraoperatively and fully understood this? Anand et al state that "none of the infants . . . displayed any clinical evidence of pain during the surgical procedure". However, they give no details of cardiovascular monitoring intraoperatively or of immediate postoperative assessments.

Although I agree with Anand et al that their work suggests that "the very substantial stress response observed in those receiving nitrous oxide and curare could imply that this commonly used anaesthetic regimen did not completely dampen the response to pain", I believe this to be only common sense and do not believe it is ethical to do this type of study to try to prove it.

I only hope that this study may at least persuade those who give anaesthesia to children (or adults) without analgesia as a major component to change that practice.

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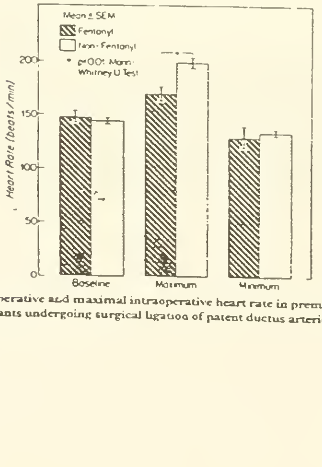
D. J. WILKINSON

**These letters have been shown to Dr Anand and colleagues, whose reply follows.—ED. L.

SIR,—Professor Lenard and Dr Wilkinson's letters raise three issues: first, surprise that in 1987 the traditional beliefs regarding pain perception in the newborn infant should still be a matter for discussion; second, the ethical justification for our study, particularly with regard to the babies given nitrous oxide and curare; and third, cardiovascular changes during surgery.

At the start of this study, we expressed exactly the same sentiments as both your correspondents. However, from a review of the literature and from discussions with colleagues it was clear that these concerns were not shared by the medical community in general or by paediatric anaesthetists in particular. Thus, the "Liverpool anaesthetic technique", using nitrous oxide and curare, was widespread. Two recent reports[1,2] are cited as examples, although several other reports have appeared in anaesthetic, surgical, and paediatric journals. Moreover, on reviewing the management of premature infants undergoing ligation of patent ductus arteriosus (PDA),[3] we were surprised to find that such major procedures were performed commonly with minimal or even no anaesthesia. In the same report, we documented for the first time that conventional anaesthesia with nitrous oxide and curare led to major metabolic and endocrine changes.[3] This preliminary study generated a hypothesis to be tested—namely, that potent anaesthesia should be given to newborn babies undergoing surgery. Our randomised trial was conducted to test this hypothesis and was designed to include only the minimum number of babies required for statistical validity. We questioned what was, and still is, accepted as a "standard" anaesthetic technique and compared it with an "experimental" anaesthetic technique involving the use of fentanyl. We suggest that our results have demonstrated unequivocally that, whereas conventional anaesthesia with nitrous oxide and curare was insufficient to prevent a major disturbance of the metabolic and endocrine milieu, the addition of fentanyl not only suppressed this stress response but also appeared to provide greater clinical stability during surgery and fewer complications postoperatively.



Preoperative and maximal intraoperative heart rate in premature infants undergoing surgical ligation of patent ductus arteriosus.

We believe that our study is defensible on ethical and scientific grounds. As physicians, it is our mandate to obtain the best possible therapy for our patients. If the best possible therapy is not known, or if current therapy is of dubious benefit, it becomes the ethical responsibility of physicians to find the optimum therapy and to obtain the formal scientific evidence for this change in practice. Our study was started only after the most thorough discussion with the doctors concerned, after formal approval by the local hospital ethics committee, and after detailed verbal and written discussion with the parents of the infants studied. We believe that we have fulfilled our ethical and scientific responsibility. Moreover, we suggest that Lenard and Wilkinson can now support their opinions on the basis of this scientific evidence.

Cardiovascular changes were observed continuously and the only significant finding was that babies in the non-fentanyl group had greater tachycardia during surgery (figure).

This discussion raises another fundamental issue—namely, the management of painful experiences in the newborn baby in circumstances other than surgery. For example, endotracheal intubation, insertion of pleural drains, and central venous, peripheral venous, and arterial cannulation are usually performed without the sedation or analgesia that would be demanded by adults. Is it not time for scientific studies to be done to examine critically the empirical management of pain and stress in the newborn infant receiving intensive care?

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CHAPTER 35

Does the newborn infant require potent anesthesia during surgery? Answers from a randomized trial of halothane anesthesia

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Introduction

Remarkably little is known about pain perception in the human fetus and newborn infant (Br. Med. J. Editorial, 1985). Early studies of neurological development concluded that the neonatal responses to painful stimuli were decorticate in nature and that perception or localization of pain was not present (Levy, 1960; Merskey, 1970). In addition, newborn infants were not thought capable of interpretation of pain, since they may not have a memory of painful experiences (Levy, 1960). Thus, it was concluded that preterm and term neonates do not require anesthesia during surgery or other invasive procedures and, in many centers, major surgery is frequently performed under the influence of minimal or no anesthesia (Lipman et al., 1976; Katz, 1977; Shaw, 1982; Anand and Aynsley-Green, 1985).

Although the use of halothane anesthesia has been recommended (Dierdorf and Krishna, 1981), early concerns about its margin of safety in neonates (Diaz and Lockhart, 1979; Gregory, 1982) led to the wider acceptance of anesthetic techniques using a combination of nitrous oxide and muscle relaxants or muscle relaxants alone for neonates undergoing surgery (Lipman et al., 1976; Katz, 1977; Shaw, 1982; Anand and Aynsley-Green, 1985). Subsequently, it was found that neonates have a much lower requirement of halothane than the concentrations which were used in earlier studies (Lerman et al., 1983). It was pointed out that unnecessarily high concentrations of halothane were used in earlier studies which had reported significant side-effects in newborn infants, thereby reflecting the effects of overdosage in this age group (Lerman et al., 1983).

No previous study has examined the hormonal and metabolic effects of the currently recommended doses of halothane, nor is its known whether halothane confers any advantage over the use of anesthesia with nitrous oxide and muscle relaxants. We report a randomized controlled trial designed to investigate the hypothesis that stress responses of neonates given halothane anesthesia do not differ from those given conventional anesthesia with nitrous oxide and curare.

Methods

Parental consent and approval of the Hospital Ethics Committee were obtained to study 36 neonates undergoing surgery (Table 1). Food was withheld for 6 h before surgery, and an intravenous dextrose infusion was maintained at 4–6 mg/kg/min throughout the study period. Blood (1–2 ml) was

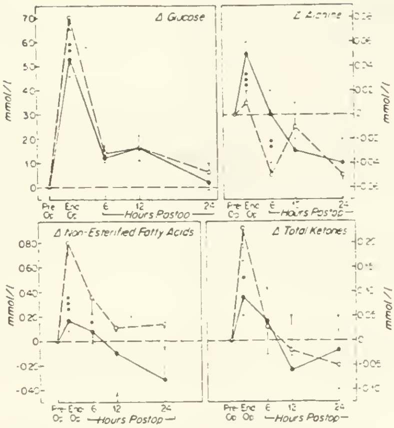

Fig 2. Comparison of changes in blood glucose, alanine, total ketone bodies, and plasma non-esterified fatty acids between neonates in the halothane (—, $n = 18$) and non-halothane (---, $n = 18$) anesthesia groups. All values are mean ± SEM. Mann-Whitney U-test ***$P < 0.02$, **$P < 0.025$, *$P < 0.05$

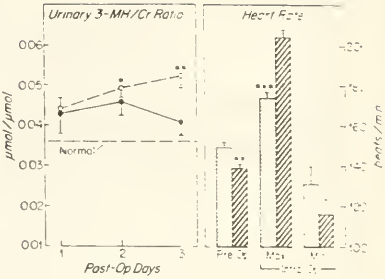

Fig 3. Comparison of changes in the heart rate during surgery and urinary 3-methylhistidine creatinine ratios postoperatively between neonates in the halothane (—, dotted columns, $n = 18$) and non-halothane (---, cross-hatched columns, $n = 18$) anesthesia groups. All values are mean ± SEM. Mann-Whitney U-test ***$P < 0.005$, **$P < 0.025$, *$P < 0.05$

group was relatively unstable during and after surgery as compared to babies in the halothane group. Several infants in the non-halothane group had increased heart rates (Fig. 3) and muscle tone during surgery, and developed respiratory and cardiovascular instability postoperatively. Postoperative analgesia was required significantly earlier by neonates in the non-halothane group; a greater number of neonates in this group required morphine analgesia and in higher daily doses during the 3 days after surgery (Table II).

Discussion

Recent studies have suggested that the measurement of physiological stress responses can provide a reliable assessment of pain in neonates undergoing surgery (Williamson and Williamson, 1983; Anand et al., 1985). These studies have also shown that provision of pain relief with local or opiate analgesic agents causes a decrease in the cardiovascular and hormonal-metabolic stress responses and may lead to an improved clinical outcome following surgery (Williamson and Williamson, 1983; Anand et al., 1987). This trial was designed to determine whether a similar effect can be obtained with potent inhalation anesthesia.

Hormonal changes
The hormonal responses of the two groups were strikingly different with regard to the catecholamine and cortisol responses during surgery. Neonates in the non-halothane group mounted epinephrine and norepinephrine responses that were respectively twice and three times those of the neonates in the halothane group. It is likely that potent anesthesia with halothane was responsible for decreasing the catecholamine and cortisol responses, similar to the observations from animal studies (Roizen et al., 1974) and adult patients (Roizen et al., 1981). A similar, though non-randomized study in older infants has also found that the cortisol responses were significantly greater in infants given nitrous oxide anesthesia as compared to those given halothane and nitrous oxide (Obara et al., 1984).

TABLE II

Postoperative clinical course

	Halothane group $n = 18$		Non-halothane group $n = 18$	
Perioperative complications:				
Persistent tachycardia	0		8	
Increased respiratory support	2		5	
Spontaneous bradycardias	2		6	
Poor peripheral circulation	0		2	
Gastric bleeding (stress ulcers?)	1		4	
Metabolic acidosis	0		2	
Paralytic ileus	0		2	
Postoperative oliguria	0		2	
Postoperative morphine requirements:				
First dose, hours after surgery	5.5 (1.6)		1.9 (0.03)**	
Total dose (mg/kg/day) on.	dose	no. of pts	dose	no. of pts
Postop day 1	0.23 (.06)	4	0.38 (.04)*	9
Postop day 2	0.10 (.03)	2	0.26 (.02)	7
Postop day 3	–	0	0.12 (.02)	4

All values = number of patients or mean (SEM).

Postoperative morphine injections were prescribed by clinical staff who were blind to the anesthetic management of each neonate. uniform criteria were used for giving postoperative analgesia to all neonates.

$^{**}P < 0.001$, $^{*}P < 0.02$, Mann-Whitney U-test.

Seven neonates were studied. Although their responses were not significant due to the small number of patients and a wide variability in their data (Obara et al., 1984). In another recent study, significant cortisol responses were observed in neonates and infants undergoing various surgical procedures (Srinivasan et al., 1986).

Plasma insulin increased in response to the hyperglycemia in both groups, but the greater insulin response in the non-halothane group could have resulted either from the stimulatory effect of hyperglycemia during surgery, which was significantly greater in the non-halothane group, or from the direct inhibition of insulin secretion by halothane (Aynsley–Green et al., 1973). However, changes in the molar insulin glucagon ratio are of greater importance than changes in the individual hormones and this ratio decreased during surgery in the non-halothane group whereas it was unchanged in the halothane group. Thus, a decrease in the insulin glucagon ratio, together with the increased cortisol and catecholamine responses would mediate a catabolic milieu in the non-halothane group during and after surgery (Sperling, 1982).

Metabolic changes

It is likely that surgical hyperglycemia was precipitated by the epinephrine release during surgery, and potentiated by the glucagon and cortisol responses in both groups of neonates (Bessey et al., 1984; Anand et al., 1985). Also, differences in the hyperglycemic response between the two groups may be explained by the significantly greater increases in plasma epinephrine and cortisol in the non-halothane group, together with a decrease in the insulin glucagon ratio. A much greater suppression of the hyperglycemic response to surgery was observed in preterm babies given fentanyl anesthesia (Anand et al., 1987).

Blood lactate and pyruvate concentrations increased during surgery in both groups, probably due to epinephrine-stimulated glycogenolysis in skeletal muscle and increased glycolysis in injured tissues (Im and Hoores, 1979). Alternatively, decreased gluconeogenesis in the liver cells (Biebuyck et al, 1972) or a decreased hepatic blood flow during halothane anesthesia (Gelman et al, 1984) may contribute to this accumulation of gluconeogenic substrates. Plasma non-esterified fatty acids increased substantially during surgery in the non-halothane group and remained elevated at 6 h after surgery, whereas only a marginal response was observed in the halothane group. These responses indicate a greater degree of lipolysis, probably mediated by the marked epinephrine release and a decrease in the insulin/glucagon ratio during surgery in the non-halothane group. Total ketone bodies also increased significantly in this group, which may be related to their greater catecholamine and glucagon responses as compared to the halothane group (Williamson, 1982).

Endogenous protein breakdown was investigated by changes in the urinary 3-MH/Cr ratio, which increased significantly in the non-halothane group and was unchanged in the halothane group. Although changes in this ratio may not specifically represent skeletal muscle breakdown, increases in the urinary 3MH/Cr ratio are associated with a negative nitrogen balance, weight loss, and poor clinical condition in newborn infants (Burgoyne et al., 1982).

Clinical observations

The heart rate increased markedly during the operation in the non-halothane group, possibly due to the intraoperative release of catecholamines in this group. The increased muscle tone observed in the non-halothane group, which required extra doses of curare during surgery, may also be as a result of light anesthesia in these neonates. Other postoperative complications documented by nursing and clinical staff in the non-halothane group established a clinical pattern that was relatively unstable as compared to neonates in the halothane group (Table II). Although postoperative morphine was prescribed by clinical personnel who were blind to the anesthetic group of each neonate and who used uniform criteria for giving analgesia to all neonates, it was surprising to find that neonates in the non-halothane group required postoperative analgesia earlier and more frequently during the 3 days after surgery than neonates in the halothane group.

Further clinical implications arise from this study in view of the existing notions of pain perception in the human neonate. It is believed widely that pain perception may be absent in newborn babies, due to either an immature central nervous system or an absence of the memory of previous painful experiences. The present study has confirmed that halothane obtunds the neonatal stress responses to surgery, thereby implying that painful stimuli may be perceived during surgery under unsupplemented nitrous oxide anesthesia which may be partially responsible for the marked stress responses. Also the efficacy of analgesia and anesthesia, particularly in paralysed and ventilated neonates, can be established reliably only by the measurement of physiological markers of stress. In conclusion, this randomized trial has rejected the hypothesis that halothane anesthesia does not alter the hormonal and metabolic stress responses of newborn infants subjected to surgery. We recommend that greater attention should be paid to the use of effective analgesia and anesthesia in newborn infants who are experiencing not only surgery, but other invasive medical procedures during intensive care. Clearly, the mechanisms of pain preception and the therapeutic management of painful experiences in neonates and children are important topics for future research.

Acknowledgements

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Metabolic and Endocrine Effects of Surgical Ligation of Patent ductus arteriosus in the Human Preterm Neonate: Are There Implications for Further Improvement of Postoperative Outcome?

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Introduction

The most commonly performed surgical procedure in the preterm neonate is thoracotomy for ligation of a patent ductus arteriosus (PDA) [1]. Although the operative mortality for this procedure is virtually absent [2], postoperative morbidity and mortality have remained relatively high during the past two decades [1, 2]. The reasons for a poor post-operative outcome are ill-defined and have usually been attributed to the complications of prematurity or the accompanying hyaline membrane disease.

Morbidity and mortality in high-risk adult patients have been related to the magnitude and duration of the endocrine and metabolic stress response precipitated by major surgery or accidental trauma [3, 4]. Manipulation of this response by the administration of deep analgesia during and after surgery has led to a decrease in postoperative catabolism and an improved clinical outcome [5].

The concept of a catabolic stress reaction to surgery assumes much greater significance in the context of the preterm neonate. The normal baby exists in a precarious metabolic state as it adapts to the postnatal environment and to postnatal nutrition [6]. Its body reserves of fat, protein and carbohydrate are limited at a time when it also has to meet the metabolic cost of rapid growth and organ maturation soon after birth. From all of this, it would seem to be particularly disadvantageous, if not life-threatening, for a seriously ill and premature neonate to experience a severe and prolonged catabolic reaction to surgery.

The stress response of preterm neonates to surgical trauma has not been studied before and this has led to empirical anaesthetic practice. The need for anaesthesia at all has been questioned [7, 8] and in some centres the premature baby may undergo ligation of a patent ductus or other forms of major surgery under the influence of muscle relaxants alone [9]. In the postoperative period, it is usual for preterm neonates to be given little in the way of analgesia, in order to avoid the potential risks of respiratory depression or hypotension. There is, however, no evidence to show that the responses of preterm neonates to painful stress are any different from those of adults.

In order to document whether this group of patients can mount a stress response to surgical trauma, we have studied 10 premature infants undergoing ligation of a patent ductus arteriosus under minimal anaesthesia. In order to further define the role of anaesthetic management on postoperative outcome, we have analysed the overall mortality data from published reports on the outcome of preterm neonates undergoing PDA ligation.

Methods

Approval of the Hospital Ethics Committee and written parental consent were obtained to study 10 preterm neonates (mean gestation 29.6 ± 0.9 weeks (± SEM), mean weight at operation 1,458 ± 294 g) undergoing PDA ligation at a mean postnatal age of 25 ± 5 days. All neonates had hyaline membrane disease and were being ventilated prior to surgery. Fluids had been restricted for 44 ± 8 h; 6 neonates had undergone a trial of intravenous indomethacin therapy (0.2 mg/kg given 12 hourly for a maximum of three doses) and all neonates were receiving diuretics for the control of congestive heart failure secondary to the PDA. None of the infants investigated was less than 750 g in weight or had experienced major stress in the form of asphyxia, hypothermia, trauma or haemorrhage within the 72 h preceding surgery.

Blood samples (0.5–1.0 ml) were drawn immediately before the induction of anaesthesia, at the end of surgery and at 6, 12 and 24 h postoperatively for the measurement of blood glucose, lactate, pyruvate, acetoacetate, hydroxybutyrate, alanine and glycerol levels by specific enzymatic methods and plasma insulin levels by radioimmunoassay.

All neonates experienced a uniform surgical procedure performed by a single surgeon; anaesthetic management was standardised to the use of *d*-tubocurarine (0.38 ± 0.12 mg/kg), nitrous oxide and oxygen (50:50). Intravenous dextrose was infused at a standard rate of 3–7 mg/kg/min during and after surgery. Postoperative analgesia was provided by morphine given as indicated by the clinical staff, but its administration was adjusted so that morphine was not injected in the 3 h preceding a postoperative blood sample. In all cases, ventilation was continued for more than 24 h after surgery.

Review of Mortality Data. A literature search was performed for reports on the postoperative outcome of preterm neonates undergoing PDA ligation. Mortality data were available from a total of 40 reports in the literature [1, 9–46, 65] and these were analysed to define chronological trends as well as the effects of anaesthetic management on postoperative outcome. Single case reports and those with insufficient information on patient outcome [47–52] were excluded from this analysis. According to their year of publication, these reports were divided into 3 chronological periods: 1970–1975, 1976–1979 and 1980–1983. The definition of anaesthetic groups was based on the predominantly used method of anaesthesia in each study. Since most reports did not contain details of the anaesthetic management of individual patients, the most popular mode of anaesthesia was assumed to represent unit policy and the anaesthetic categories were allocated accordingly.

For purposes of analysis, anaesthetic management was broadly defined into two categories: (I) in which no anaesthesia or minimal anaesthesia using nitrous oxide was administered during PDA ligation [9–32, 42, 44, 65] and (II) in which neonates received potent anaesthetic agents such as halothane, enflurane, morphine or ketamine [1, 33–41, 43, 45]. In one report [38] the operative procedure was carried out under local anaesthesia; the results from this were included in category II since it is expected that painful stimuli from the surgical trauma were almost completely abolished by infiltration with lignocaine and since adult studies have shown that local or epidural analgesia may even abolish the catabolic stress reaction to surgery [5]. The hormonal and metabolic data were analysed by Wilcoxon's signed-ranks test and the reviewed mortality data were analysed by the χ^2 test [53].

Results

The mean duration of surgery for PDA ligation in our study was 21 ± 4 min and the estimated blood loss was 5 ± 1 ml. According to a previously established stress-scoring method [54], all infants were assessed to have been subjected to moderate surgical stress (score 6–10) and had a mean score of 7.3 ± 0.4 (± SEM). No infant died in the present study.

Hormonal and Metabolic Response

The results of hormonal and metabolic analyses are listed in table I. Blood glucose concentrations increased significantly ($p < 0.005$) from a pre-operative level of 4.6 ± 0.5 to 10.3 ± 1.3 mmol/l at the end of surgery and remained significantly elevated at 6 h ($p < 0.025$), 12 h ($p < 0.005$) and 24 h ($p < 0.025$) after surgery (fig. 1). There was also a significant rise in the blood levels of lactate ($p < 0.005$), pyruvate ($p < 0.005$), total ketone bodies (acetoacetate and hydroxybutyrate) ($p < 0.025$) and glycerol ($p < 0.005$) by the end of the operative procedure, but by 6 h postoperatively the levels of all these metabolites had reverted to their pre-operative values (fig. 1–3). There was no significant alteration in blood alanine concentration during or after surgery (fig. 2).

The levels of plasma insulin (table II) did not change significantly during surgery or in the postoperative period (fig. 4) and, consequently, the molar insulin/glucose ratio was significantly decreased at the end of surgery ($p < 0.005$) (fig. 5).

Table I. Metabolic changes in preterm neonates undergoing ligation of a patent ductus arteriosus (mean ± SEM, n = 10, Wilcoxon's matched-pairs signed-ranks test)

Metabolites mmol/l	Pre-op.	End-op.	6-hour postop.	12-hour postop.	24-hour postop.
Glucose	4.6 ± 0.5	10.3 ± 1.3 p<0.005	8.1 ± 2.2 p<0.025	7.1 ± 1.0 p<0.005	7.3 ± 1.5 p<0.025
Lactate	1.5 ± 0.1	2.6 ± 0.3 p<0.005	1.6 ± 0.3 n.s.	1.5 ± 0.2 n.s.	1.5 ± 0.2 n.s.
Pyruvate	0.10 ± .01	0.14 ± .02 p<0.005	0.12 ± .01 n.s.	0.12 ± .01 n.s.	0.12 ± .02 n.s.
Alanine	0.17 ± .03	0.17 ± .04 n.s.	0.15 ± .03 n.s.	0.16 ± .03 n.s.	0.14 ± .03 n.s.
Total ketones	0.19 ± .04	0.36 ± .12 p<0.025	0.20 ± .04 n.s.	0.18 ± .05 n.s.	0.14 ± .03 n.s.
Glycerol	0.14 ± .03	0.21 ± .02 p<0.005	0.16 ± .03 n.s.	0.14 ± .02 n.s.	0.11 ± .02 n.s.

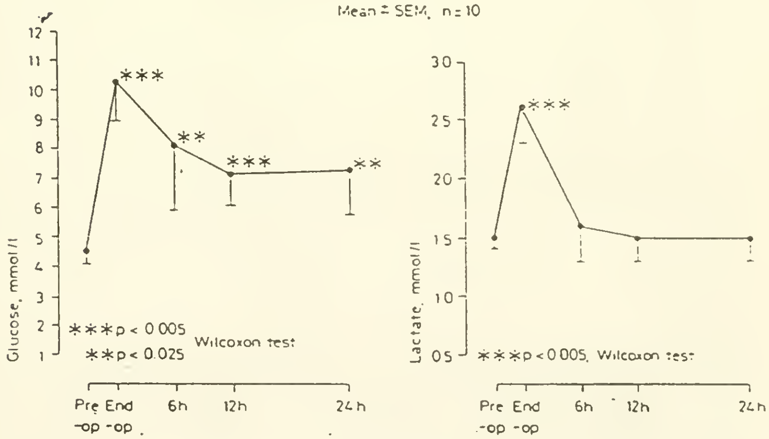

Fig. 1. Levels of blood glucose and blood lactate in preterm neonates undergoing PDA ligation.

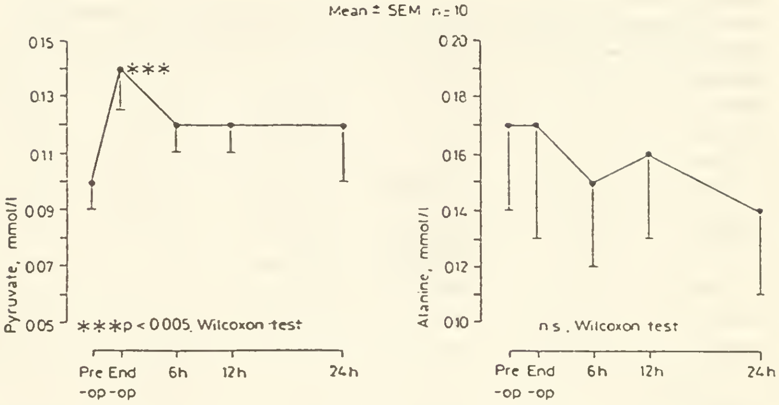

Fig. 2. Levels of blood pyruvate and blood alanine in preterm neonates undergoing PDA ligation.

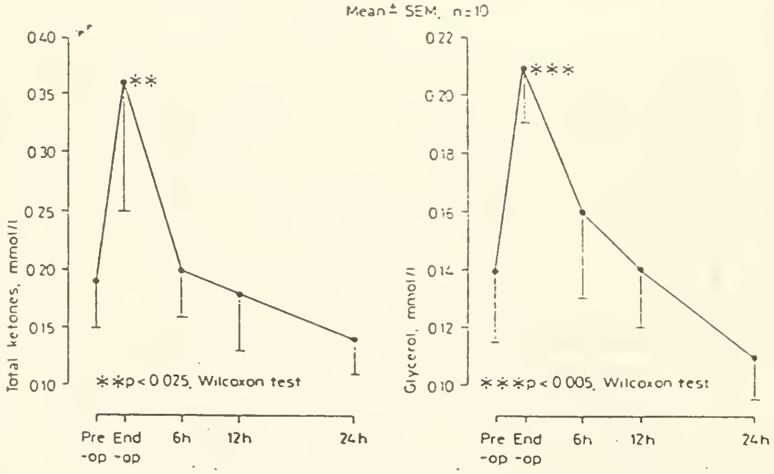

Fig. 3. Levels of total ketones (acetoacetate and hydroxybutyrate) and blood glycerol before and after thoracotomy for PDA ligation in preterm neonates.

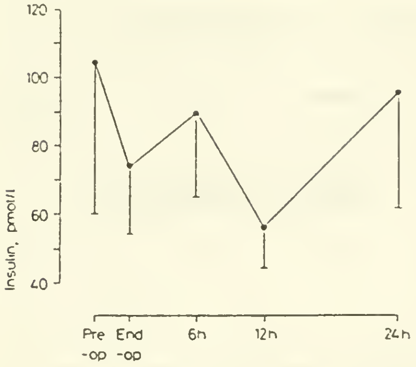

Fig. 4. Plasma insulin concentrations in preterm neonates undergoing PDA ligation. (Mean ± SEM, n = 9).

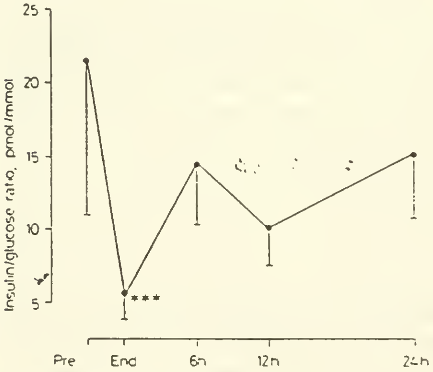

Fig. 5. Changes in insulin/glucose ratio in preterm neonates undergoing PDA ligation. (Mean ± SEM, n = 9, Wilcoxon's matched-pairs signed-ranks test: $p < 0.005$).

Review of Mortality

From published reports on the postoperative outcome of 1,157 preterm neonates undergoing ligation of a PDA 287 deaths were recorded giving rise to an overall mortality of 25%. There was no significant correlation between the individual mortality rate in each study and the mean weight of patients in that study.

Table II. Endocrine changes in preterm neonates undergoing ligation of a patent ductus arteriosus (mean ± SEM, n = 9, Wilcoxon's matched-pairs signed-ranks test)

	Pre-op.	End-op.	6-hour postop.	12-hour postop.	24-hour postop.
Insulin pmol/l	104 ± 45	74 ± 20 n.s.	90 ± 25 n.s.	56 ± 12 n.s.	95 ± 33 n.s.
Insulin/glucose ratio, pmol/mmol	21.2 ± 10.2	5.4 ± 1.7 $p<0.005$	14.5 ± 4.2 n.s.	10.1 ± 2.5 n.s.	15.1 ± 4.2 n.s.

On dividing the material into three chronological periods, the overall mortality rate in 1970–1975 was 34% ($n = 198$), in 1976–1979 mortality was 33% ($n = 349$), and had decreased significantly to 17% ($p < 0.001$; $\chi^2 = 39.03$) in the period 1980–1983 ($n = 610$) (fig. 6). On re-analysis of this data according to the different categories of anaesthetic management, overall postoperative mortality in the group receiving no anaesthesia or minimal anaesthesia during surgery was 26% ($n = 877$) and in the group administered potent anaesthetic agents during surgery it was 21% ($n = 280$). The difference in mortality between the two anaesthesia groups was not significant ($p > 0.05$; $\chi^2 = 2.497$).

Discussion

The endocrine and metabolic response of preterm neonates subjected to anaesthesia and surgery has not been investigated previously. Since post-traumatic morbidity and mortality in high-risk adult patients have been related to the magnitude and duration of their catabolic stress response, it is imperative that such relationships, if they exist, should be established for the sick premature infant so that therapeutic measures may be considered for modification of the neonatal stress response.

The preterm neonates included in this study were very similar in their clinical condition at the time of surgery, they experienced the same surgical procedure and virtually the same anaesthetic management. Other factors which could affect peri-operative metabolism, particularly intravenous fluid therapy and postoperative analgesia, were standardised for all neonates investigated. Parenteral nutrition solutions containing amino acids or soluble fats were not given from 6 h pre-operatively up to 24 h after surgery.

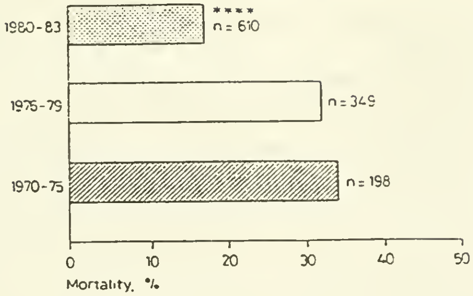

Fig. 6. Chronological trends from review of published postoperative mortality data following ligation of patent ductus arteriosus in preterm neonates. 287 deaths were recorded from the postoperative outcome of 1.157 neonates undergoing PDA ligation. (Overall mortality: 1970–75 = 34%, 1976–79 = 32% 1980–83 = 17%.
χ^2 test: $p << 0.001$, $\chi^2 = 39.03$.)

The most prominent catabolic effect that we have documented is the development of a highly significant hyperglycaemia during surgery (fig. 1) which persisted for more than 24 h following surgery. The mechanism of post-surgical hyperglycaemia can be explained on the basis of stress-related changes in the secretion of insulin and the counter-regulatory hormones [55]. Despite the marked increase in blood glucose concentrations, insulin levels did not change during surgery or in the postoperative period (fig. 4). Consequently, the insulin/glucose molar ratio decreased significantly at the end of surgery and remained low thereafter (fig. 5). The total lack of insulin secretion in response to post-surgical hyperglycaemia may either be due to a decreased responsiveness of beta-cells in the premature pancreas which has been documented previously [66], or may possibly be caused by a direct inhibition of insulin secretion by adrenaline release during surgery [67]. It is not known whether handling of the vagus nerve which occurs during PDA ligation has any role to play in the inhibition of insulin secretion after surgery.

Due to constraints on the volume of blood sampling, the counter-regulatory hormones, glucagon and the catecholamines were not measured in this study. In a previous report, however, we have proposed that post-surgical hyperglycaemia in newborn infants is initiated by adrenaline release during surgery and is maintained into the postoperative period by glucagon secretion [54]. Studies of postoperative glucose turnover using stable isotopes will be required to define whether these changes are predominantly due to increased endogenous glucose production or decreased peripheral utilisation in the preterm neonate.

Associated with the increase in blood glucose concentration, significant increases in blood lactate and pyruvate levels were seen immediately after surgery (fig. 1, 2). The increased production of these metabolites may be related to alterations in glucose homeostasis in response to surgical stress. Studies in adult surgical patients have shown that adrenaline release during surgery causes an increased production of lactate and pyruvate in skeletal muscles [56]. As shown by double-isotope turnover studies in neonates [57], these metabolites are removed from the circulation by the liver to be used as substrates for hepatic gluconeogenesis and thus may contribute towards the postoperative hyperglycaemia [58].

In addition to causing an exhaustion of carbohydrate reserves in the preterm neonate, the substantial and prolonged hyperglycaemic response may have important clinical implications due to its effect on plasma osmolality [59]. In preterm neonates, the association of hyperlactataemia [60] together with a rapid increase in plasma osmolality [61] may have deleterious effects on the renal cortex and cerebral substance and may even lead to intraventricular haemorrhage [62].

The significant increase in the blood levels of total ketone bodies and glycerol at the end of surgery (fig. 3) was probably a consequence of lipolysis and ketogenesis stimulated by catecholamine release during surgery [54]. The metabolism of ketone bodies in peripheral tissues, through the formation of citrate and inhibition of phosphofructokinase, may further inhibit the peripheral utilisation of glucose and contribute towards the postoperative hyperglycaemia in neonates [63]. Studies of glycerol turnover in newborn infants have shown that 75% of glycerol thus formed enters the gluconeogenic pathway in the neonatal liver and contributes to 5% of hepatic glucose production [64]. At present it is not known whether all these metabolic pathways are completely functional in the premature infant. From these data, therefore, we propose that preterm infants subjected to thoracotomy under minimal anaesthesia can mount a substantial stress response which is characterised by hyperglycaemia, hyperlactataemia, hyperketonaemia, together with increases in blood glycerol and blood pyruvate, and the inhibition of insulin secretion.

It is not possible to objectively equate the degree of surgical stress experienced by preterm neonates during PDA ligation with the stress of a particular surgical procedure in adult patients; therefore, a strict comparison of the metabolic stress response of premature infants with that of adults is difficult, and may even be unscientific. However, data from adult studies suggest that a similar magnitude of metabolic change in adult patients would be associated with surgical procedures of much greater severity than a simple thoracotomy. Although the suppression of insulin secretion and post-surgical hyperglycaemia persist for a longer period than in adults, other features of the metabolic stress response are short-lasting in the preterm neonate. It is possible that this pattern of metabolic change is perhaps a consequence of the minimal anaesthesia that was given during surgery.

In this study, anaesthesia was provided by nitrous oxide, oxygen and *d*-tubocurarine as is the current practice in our hospital for preterm infants. For infants with a high oxygen requirement, lower concentrations of nitrous oxide were used in order to maintain adequate oxygenation. Moreover, at certain stages of the surgical procedure, for example during retraction of the left lung, the flow of nitrous oxide was decreased and occasionally stopped altogether. This anaesthetic method is the most widely used technique for premature babies, and as shown by our literature search, was employed for 76% preterm neonates undergoing thoracotomy for ligation of a PDA. It has been questioned whether the preterm neonate is capable of feeling or discriminating pain and whether anaesthesia is necessary at all during surgery [7].

From adult patients undergoing major surgical or accidental trauma it is evident that a number of complications may be precipitated by the endocrine and metabolic response to surgical stress. These include severe weight loss, cardiopulmonary insufficiency, thromboembolism, gastric stress ulcers, impaired immunological function, prolonged fatigue and convalescence [3]. Moreover, post-traumatic morbidity and mortality in high-risk patients have been related to metabolic parameters of the stress response [4]. Consequently, specific anaesthetic techniques have been recently developed in order to inhibit the stress response of high-risk adult patients undergoing major surgery [3]. It is presently not known whether inhibition of the stress response in preterm neonates will lead to a decrease in postoperative complications and an improvement of post-surgical morbidity and mortality.

The mortality data from the published literature on PDA ligation was analysed in order to define chronological trends and the effects of anaesthetic management. The clinical outcome in terms of morbidity could not be studied since a uniform measure of morbidity was not applicable to all published reports. On analysis of the pooled mortality data, there was no significant difference between the survival of neonates given 'inadequate' anaesthesia and those given 'adequate' anaesthesia. The lack of difference between these groups is not surprising since the anaesthetic agents given to the latter group were not sufficient to inhibit the endocrine-metabolic stress response at all. In adult subjects, inhibition of the stress response can only be obtained by high-dose narcotic anaesthesia or epidural analgesia. Moreover, it is probable that the premature infants included in this analysis from the various published reports were a heterogenous group of patients and that there was a wide variation in the clinical practices followed by different neonatal units. It is also possible that the published postoperative outcome in each report is not strictly representative of the outcome of all preterm neonates undergoing PDA ligation in that particular centre.

The chronological trend observed in this analysis, showing a substantial decrease in postoperative mortality during the period 1980–1983 was expected. This is due not only to recent advances in surgical technique and neonatal care, but also due to the development of sophisticated monitoring techniques, optimum ventilatory management, intravenous feeding and the availability of safe and effective antibiotics. The trend for earlier ligation of a PDA as well as previous indomethacin therapy may also have some effect on the postoperative outcome [51].

Nonetheless, the present study has confirmed that the human preterm neonate subjected to surgical stress under minimal anaesthesia mounts a substantial and prolonged catabolic reaction in the postoperative period. Given the beneficial effects of modification of the endocrine-metabolic stress response of adult patients, it needs to be investigated whether manipulation of the surgical stress response of preterm neonates will have any beneficial effects on postoperative morbidity and mortality.

Acknowledgements

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Can the Human Neonate Mount an Endocrine and Metabolic Response to Surgery?

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England

● Little is known of the ability of the human newborn infant to mount an endocrine and metabolic response to surgical trauma. Blood concentrations of glucose, lactate, pyruvate, alanine, hydroxybutyrate, acetoacetate, and glycerol together with plasma concentrations of insulin, glucagon, adrenaline, and nonadrenaline were measured in 33 infants (26 term, 7 preterm) subjected to surgery during the neonatal period. The results show that newborn infants can indeed mount a substantial endocrine and metabolic stress response, the main features of which are hyperglycemia and hyperlactatemia associated with the release of catecholamines end the inhibition of insulin secretion. There are specific differences between preterm and term neonates and between neonates anesthetised by different anesthetic techniques in the pettern of this response.

INDEX WORDS: Neonatal surgery stress response.

IN ADULT PATIENTS subjected to surgery the plasma levels of cortisol, catecholamines, glucagon, prolactin, and growth hormone increase perioperatively, whereas insulin secretion is suppressed.[1,2] These hormonal changes trigger a cascade of metabolic adjustments resulting in endogenous protein breakdown, glycogenolysis, gluconeogenesis, and lipolysis. This endocrine-metabolic response is not always beneficial and may precipitate a number of undesirable effects including increased morbidity and mortality in high-risk adult patients.[3,4]

The catabolic stress reaction to surgery assumes greater significance in the context of newborn infants. The normal neonate exists in a precarious metabolic milieu as it adapts both to the postnatal environment and to postnatal nutrition.[5] Moreover, the infant's body reserves of carbohydrate, fat, and protein are limited at a time when it has to meet the metabolic cost of rapid growth and organ maturation. It would seem, therefore, to be particularly disadvantageous, if not life-threatening, for a seriously ill or premature neonate to experience a severe and prolonged catabolic reaction to surgery. This contention is supported by the higher morbidity and mortality that occurs in neonates than in older children or adults subjected to similar surgical procedures.[6-10]

Little is known of the neonatal endocrine and metabolic response to surgery and this has led to empirical anesthetic practice. Thus it is recommended that as light an anesthetic as possible should be given to neonates;[11-15] even the need for anesthesia at all has been questioned and, in some centers, major surgery is performed on sick and premature neonates under the influence of muscle relaxants alone.[16-18] This study was designed to help resolve some of these controversies.

MATERIALS AND METHODS

With the Ethics Committee approval and with parental consent, 33 neonates undergoing surgery (26 term and 7 preterm; mean birthweight 3.0 ± 0.1 kg and 1.5 ± 0.1 kg, mean postnatal age 14 ± 3 and 32 ± 5 days, respectively) were studied. Infants born small for gestational age were excluded from the study. None of the infants experienced metabolic abnormalities or asphyxia, hypothermia, trauma, or hemorrhage within the 72 hours preceding surgery.

Venous blood samples were drawn immediately before the induction of anesthesia, at the end of surgery, and at 6, 12, and 24 hours following surgery. Blood levels of glucose, lactate, pyruvate, alanine, hydroxybutyrate, acetoacetate and glycerol were measured by specific enzymatic methods.[19] plasma levels of insulin and glucagon were measured by radioimmunoassay[20,21]; adrenaline and noradrenaline by a double-isotope radio-enzymatic assay.[22]

Premedication was with atropine (0.02–0.04 mg/kg) alone. Anesthetic agents were limited to the use of thiopentone, halothane, d-tubocurarine, and nitrous oxide; opiates were not given. Intravenous dextrose was infused at a standard rate of 3 to 7 mg/kg/min. Following surgery, intramuscular injections of omnopon or morphine were given postoperatively as indicated but their administration was adjusted so

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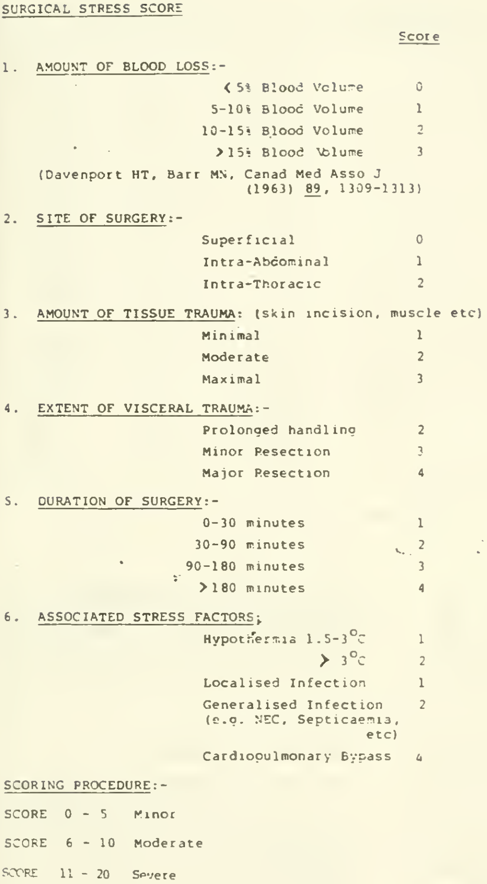

SURGICAL STRESS SCORE

		Score
1. AMOUNT OF BLOOD LOSS:-		
	< 5% Blood Volume	0
	5-10% Blood Volume	1
	10-15% Blood Volume	2
	> 15% Blood Volume	3
(Davenport HT, Barr MN, Canad Med Asso J (1963) 89, 1309-1313)		
2. SITE OF SURGERY:-		
	Superficial	0
	Intra-Abdominal	1
	Intra-Thoracic	2
3. AMOUNT OF TISSUE TRAUMA: (skin incision, muscle etc)		
	Minimal	1
	Moderate	2
	Maximal	3
4. EXTENT OF VISCERAL TRAUMA:-		
	Prolonged handling	2
	Minor Resection	3
	Major Resection	4
5. DURATION OF SURGERY:-		
	0-30 minutes	1
	30-90 minutes	2
	90-180 minutes	3
	> 180 minutes	4
6. ASSOCIATED STRESS FACTORS:		
	Hypothermia 1.5-3°C	1
	> 3°C	2
	Localised Infection	1
	Generalised Infection (e.g. NEC, Septicaemia, etc)	2
	Cardiopulmonary Bypass	4

SCORING PROCEDURE:-

SCORE	0 - 5	Minor
SCORE	6 - 10	Moderate
SCORE	11 - 20	Severe

Fig 1. Surgical stress score.

that they were not injected in the 3 hours preceding a postoperative blood sample.

The extent of operative stress was calculated by using a scoring method based on factors that contribute to the stress of surgical trauma (Fig 1), together with others specific for neonatal patients. According to this score, the magnitude of surgical stress was minor (score 0–5) in 9 patients, moderate (score 6–10) in 20 patients, and severe (score 11–20) in 4 patients. The results were analyzed by the nonparametric Wilcoxon, Mann-Whitney U, and Spearman rank coefficient tests.

RESULTS

Overall Data

The results of metabolic and hormonal analysis from all 33 patients are listed in Table 1. Blood glucose concentrations increased significantly at the end of surgery, and remained elevated at 6 hours and 12 hours postoperatively. There was a significant increase in blood concentrations of lactate, pyruvate, total ketone bodies

Table 1. Perioperative Changes in Blood and Plasma Concentrations of Metabolic Fuels and Hormones in Neonates Subjected to Surgery

		N	Pre-op*	End-op	6 hr	12 hr	24 hr
Metabolic Changes							
Glucose	mmol/L	33	4.8 ± 0.2	11.1 ± 1.0 *P* << .001**	7.0 ± 0.9 *P* < .001	7.6 ± 1.4 *P* < .001	5.5 ± 0.5 NS
Lactate	mmol/L	33	1.6 ± 0.1	2.9 ± 0.3 *P* << .001	2.1 ± 0.3 *P* < .05	2.0 ± 0.2 *P* < .01	1.8 ± 0.2 NS
Pyruvate	mmol/L	33	0.10 ± .01	0.16 ± .02 *P* << .001	0.13 ± .01 NS	0.13 ± .01 NS	0.11 ± .01 NS
Alanine	mmol/L	33	0.22 ± .01	0.24 ± .02 NS	0.24 ± .02 NS	0.25 ± .03 NS	0.2[illegible] ± .01 NS
Total ketones	mmol/L	33	0.18 ± .02	0.30 ± .05 *P* < .005	0.17 ± .02 NS	0.17 ± .03 NS	0.16 ± .02 NS
Glycerol	mmol/L	33	0.17 ± .02	0.25 ± .03 *P* < .005	0.17 ± .02 NS	0.19 ± .02 NS	0.16 ± .02 NS
Hormonal Changes							
Adrenaline	ng/mL	14	0.08 ± .02	0.44 ± .17 *P* < .001	0.08 ± .02 NS	0.05 ± .01 NS	0.08 ± .04 NS
Nonadrenaline	ng/mL	14	0.81 ± .14	1.62 ± .41 *P* < .005	1.23 ± .32 NS	1.35 ± .42 NS	0.87 ± .12 NS
Insulin	mU/L	27	12 ± 2	15 ± 3 NS	21 ± 4 NS	17 ± 4 *P* < .025	22 ± 4 *P* < .025
Glucagon	pmol/L	7	29 ± 6	31 ± 7 NS	23 ± 5 NS	16 ± 5 NS	16 ± 5 *P* < .025

*All values Mean ± SEM

†Wilcoxon's matched-pairs signed-ranks test from preoperative values.

(acetoacetate and hydroxybutyrate), and glycerol during surgery. Levels of blood lactate remained elevated until 12 hours after surgery whereas all other metabolites reverted to preoperative levels by 6 hours postoperatively. No significant changes were seen in blood alanine concentration during or after surgery.

There was a highly significant increase in plasma adrenaline and noradrenaline concentrations at the end of surgery, but the levels of plasma insulin and glucagon did not change in the immediate perioperative period. By 12 hours following surgery, a significant increase was recorded in insulin levels which was maintained up to 24 hours postoperatively whereas glucagon levels had decreased significantly by 24 hours postoperatively.

Blood glucose concentrations were strongly correlated with plasma adrenaline (Fig 2) at the end of surgery ($r_s = 0.95$, N = 14, $P < 0.0001$) and with plasma glucagon at 6 hours postoperatively ($r_s = 0.86$, N = 7, $P < 0.05$). Levels of blood lactate were correlated with plasma adrenaline concentrations at the end of surgery ($r_s = 0.61$, N = 14, $P < 0.025$) and 6 hours after surgery ($r_s = 0.70$, N = 11, $P < 0.01$). A significant correlation was also present between blood glycerol levels and plasma adrenaline ($r_s = 0.76$, N = 14, $P < 0.005$) and noradrenaline ($r_s = 0.63$, N = 14, $P < 0.01$) at the end of surgery.

Preterm and Term Neonates

Values relating to 6 preterm and 6 term neonates were compared; all had experienced moderate surgical stress (score 6–10) and had received the same anesthetic technique (nitrous oxide, d-tubocurarine, and oxygen).

There was no significant difference between preterm and term neonates in blood glucose (Fig 3), pyruvate, total ketone bodies, and glycerol levels before or after surgery. However, blood lactate concentrations increased significantly in preterm neonates during surgery and did not change in the term neonates. Postoperatively, blood levels of alanine increased in the term neonates ($P < 0.025$) whereas no change occurred in the preterm neonates (Fig 3). Plasma insulin levels increased markedly in the term

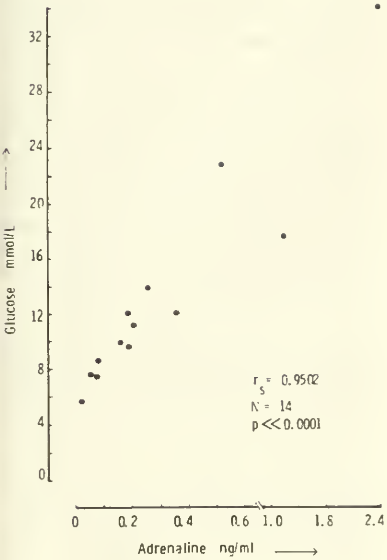

Fig 2. Correlation between blood glucose and plasma adrenaline concentrations at the end of surgery. The Spearman rank correlation coefficient (r_s) was calculated from the data of 14 patients in whom catecholamine levels were measured and was highly significant ($P \ll 0.0001$).

neonates and were significantly higher than in preterm neonates at the end of surgery through to 24 hours after surgery (Fig 4).

Specific Anesthetic Techniques

In the group of term neonates undergoing moderate surgical stress (score 6–10), there were 6 who received an anesthetic regimen of halothane (1% to 2% for induction, 0.5% for maintenance), nitrous oxide (50%), d-tubocurarine, and oxygen; and another 5 who received thiopentone (4 to 5 mg/kg for induction, 1 to 2 mg/kg supplement if surgery lasted over one hour), nitrous oxide (50%), d-tubocurarine, and oxygen. The results from these groups were therefore compared.

Neonates who received thiopentone anesthesia experienced a significantly greater glycemic response than those who received halothane (Fig 5). There were no significant differences between the two groups in the blood levels of lactate, pyruvate, alanine, total ketones, and glycerol before or after surgery. Moreover, no significant differences were found in the plasma insulin levels of the two groups perioperatively (Fig 5).

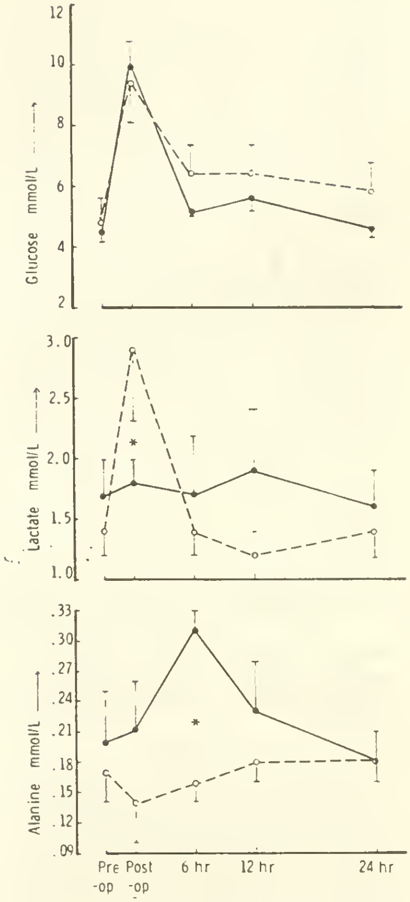

Fig 3. Comparison of metabolic changes in preterm (O---O, N = 6) and term (●——●, N = 6) neonates (*$P < 0.05$, Mann-Whitney U test).

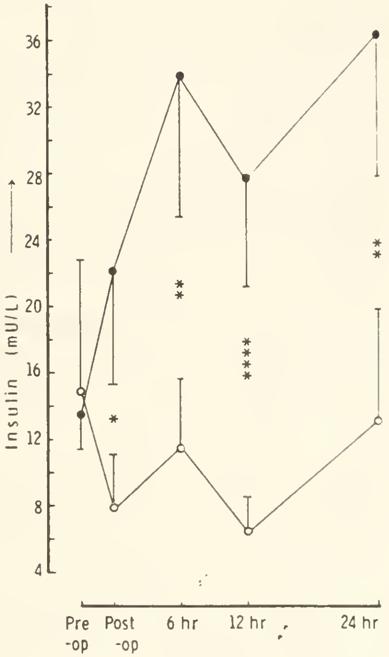

Fig 4. Comparison of changes in plasma insulin between preterm (○—○, N = 6) and term (●—●, N = 6) neonates (*$P < 0.05$, **$P < 0.025$, ****$P < 0.001$, Mann-Whitney U test).

DISCUSSION

Remarkably little is known of the metabolic and endocrine responses of human neonates subjected to surgery. In studies that can be criticized on methodological grounds, Elphick[23-25] and Pinter[26-30] showed that blood glucose levels increased during surgery and remained elevated for several hours even though glucose clearance rates were not altered. No consistent changes occurred in the levels of blood lactate, urea, plasma amino acids, or free fatty acids. Blood triglycerides decreased postoperatively, whereas other neutral lipids were unaltered. From these studies, it was concluded that anesthesia and surgery in the neonate caused a short-lasting metabolic disturbance, the cause and consequences of which were unclear. These studies represent the only previous attempts to define the metabolic responses of newborn infants to surgical trauma.

In this study, the various factors that could affect perioperative metabolism apart from anesthesia and surgery were standardized as far as possible. Preoperative starvation was limited to 4 hours, perioperative fluid therapy was adjusted in order to deliver dextrose at a rate of 3 to 7 mg/kg/min, parenteral nutrition was not given, and the timing of postoperative analgesia was adjusted so as to have no anticipated effect on the hormonal or metabolic variables measured

The most consistent metabolic effect documented is the development of postoperative hyperglycemia. The mechanism of this can be considered in relation to the concurrent changes in the secretion of insulin and the counter-regulatory hormones.[31] At the end of surgery, the strong correlation between blood glucose and plasma adrenaline values implies that the hyperglycemic response may be precipitated by adrenaline release during surgery. However, within 6 hours the blood glucose concentrations were only poorly related to adrenaline levels, but were significantly related to plasma glucagon concentrations. We propose therefore that postsurgical hyperglycemia in neonates is initiated by adrenaline release and is maintained into the early postoperative period by glucagon secretion. Of greater potential importance, however, is the apparent lack of insulin secretion during surgery and in the early postoperative period, probably due to a direct inhibition of insulin secretion by adrenaline. Consequently, the insulin/glucose molar ratio decreased significantly at the end of surgery (Fig 6), reflecting inappropriately low insulin levels for the circulating glucose concentrations. However, insulin levels were found to be significantly elevated at 12 and 24 hours postoperatively, thereby restoring blood glucose to normal levels.

The substantial hyperglycemic response, particularly in the severe surgical stress group has important clinical implications due to its effect on plasma osmolality In newborn infants, an increase in plasma osmolality of greater than 25 mOsmols/kg H_2O over a period of 4 hours can have detrimental effects on the renal cortex and

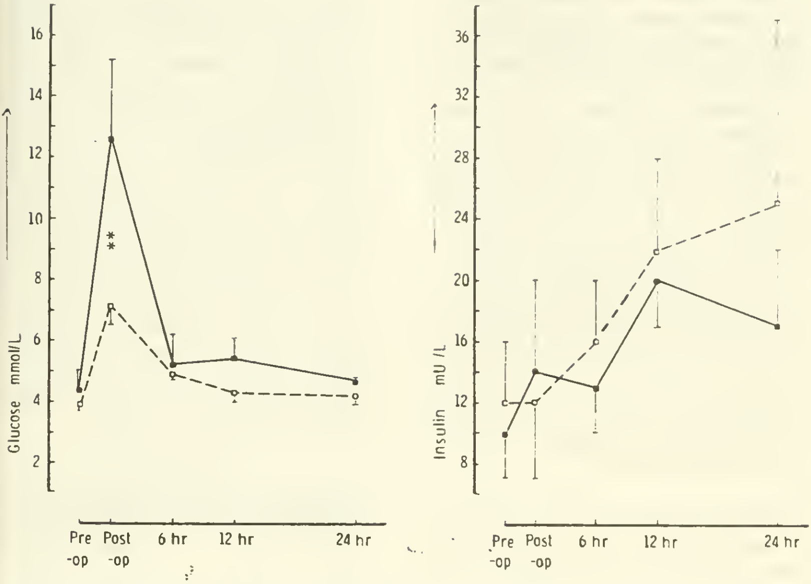

Fig 5. Comparison of changes in blood glucose and plasma insulin between groups of neonates anesthetised with either Thiopentone (■—■, N = 5) or Halothane (□---□, N = 6) ($^{**}P < 0.025$, Mann-Whitney U test).

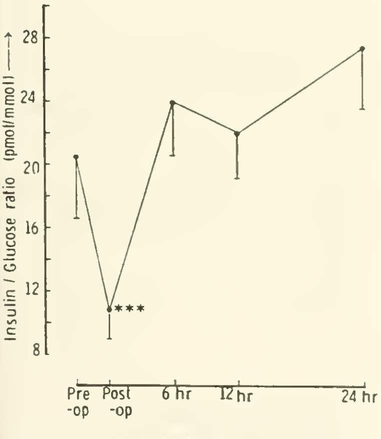

Fig 6. Changes in insulin/glucose ratio in newborn infants (N = 27) undergoing surgery ($^{***}P < 0.005$, Wilcoxon's matched-pairs signed-ranks test).

cerebral substance and may even lead to intraventricular hemorrhage.[32-33]

Concurrent with postoperative hyperglycemia were significant increases in blood lactate and pyruvate concentrations. Plasma adrenaline and blood lactate levels correlated significantly at the end of surgery and 6 hours postoperatively, suggesting a cause and effect relationship. There may be a physiological role for these changes since lactate and pyruvate form important substrates for hepatic gluconeogenesis in the postoperative period.

The increase in blood total ketone body and glycerol levels during surgery probably reflects catecholamine-stimulated lipolysis and ketogenesis, further evidence for this being the strong correlation of blood glycerol concentrations with plasma adrenaline and noradrenaline levels at the end of surgery.

Comparison of Preterm and Term Neonates

The metabolic response to surgery in preterm neonates was not very different from that of term neonates. Glucose levels increased equally in both groups, although there was a trend toward greater postoperative hyperglycemia in the former. Preterm neonates also developed a significant degree of hyperlactatemia during surgery, possibly due to deficiency of the key hepatic gluconeogenic enzymes.

Turnover studies using stable isotopes will be needed to clarify the mechanism of these changes and the differences in alanine levels between the groups.

Finally, insulin levels increased postoperatively in the term neonates but did not change in the preterm neonates. This finding, possibly due to a decreased responsiveness of beta-cells in the premature pancreas,[34] may explain the tendency of preterm neonates to maintain higher blood glucose levels than term neonates during the postoperative period. The deleterious effects of a hyperosmolar state and lactic acidaemia are of even greater potential significance in this group than in full-term infants.

Comparison of Specific Anesthetic Techniques

The only significant difference between neonates anesthetised with thiopentone and halothane was a greater hyperglycemia at the end of surgery in the former group. This effect was short-lasting and, by 6 hours after surgery, blood glucose levels in both groups were similar. Since there was no difference in the insulin levels it is possible that this was a direct effect of thiopentone on glucose metabolism, as has been suggested in adult subjects.[35,36]

In conclusion, this study has demonstrated the ability of the human neonate to mount an endocrine and metabolic response to surgery. There are specific differences between preterm and term neonates and between neonates anesthetized by different anesthetic techniques in the pattern of this response. Further detailed studies are needed to define more precisely the effects of other surgical, anesthetic, and analgesic circumstances. Such data may help to develop specific regimens for different groups of infants and lead to an improved postoperative outcome.

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NEONATAL AND PEDIATRIC STRESS RESPONSES TO ANESTHESIA AND OPERATION

K. J. S. Anand, M.B., B.S., D. Phil., and M. P. Ward-Platt, M.B., Ch.B., M.R.C.P.

The hormonal-metabolic stress response of adult patients undergoing an operation and its modification by general anesthesia, regional anesthesia, and graded surgical stress have been described in accompanying chapters of this volume. Surgical or nonsurgical injury triggers the release of "stress hormones" (catecholamines, corticosteroids, growth hormone, and glucagon), which stimulate a cascade of metabolic changes leading to substrate mobilization with the breakdown of protein, fat, and carbohydrate stores. These metabolic changes are one component of the global response to injury (including cardiovascular and immunological phenomena) that in a nonhospital setting, may facilitate wound repair and eventual recovery [1]. In a hospital setting, these responses serve no useful function and, particularly following major surgery, may lead to a pathological degree of metabolic instability associated with an increased morbidity and mortality. In pediatric patients, metabolic stability is much more difficult to maintain because of (1) a relatively greater surface area, necessitating greater heat production; (2) a larger brain to body weight ratio, with increased obligatory requirements for glucose, (3) the need to maintain somatic growth; and (4) relatively smaller reserves of protein, carbohydrate, and fat. In newborns, the adaptation to extrauterine life, enteral nutrition, and rapid organ maturation impose a much greater susceptibility to the metabolic and physiological insult caused by surgical procedures [2, 3]. In this context, it is not surprising that a greater incidence of postoperative complications and mortality have been documented in preterm and term neonates undergoing surgical procedures [4, 5].

Despite their clinical importance, there are few published data on the stress responses of pediatric patients undergoing anesthesia and operation [6]. In this review, the stress response of neonates is discussed separately from those of older infants and children. This division is somewhat artificial, since an ontogeny of the stress response can be discerned, beginning from the distinct fetal responses, through changing patterns of responses in neonates and young children, to the development of adult-type stress responses in postpubertal children. Important clinical implications arise from these differences between pediatric and adult stress responses that have a bearing on current anesthetic practice.

STRESS RESPONSES IN THE NEONATE

Fetal Stress Responses

Consideration of the endocrine-metabolic stress response in neonates must include data pertaining to the fetus for several reasons. First, the effects of surgery in the premature neonate may be better defined in terms of "fetal" rather than "neonatal" physiology. Second, even the in utero fetus has been subjected to invasive procedures such as intraperitoneal blood transfusion, percutaneous cystostomy, and more complex operations [7]. Recent data on metabolic homeostasis in the early fetus showed that the human fetus was a net producer of glucose and lactate as early as 16 to 18 weeks of gestation [8]. Coupled with the capability of mounting catecholamine [9] and corticosteroid [10] responses during early fetal life, these data imply that the endocrine control of metabolic homeostasis may already be functional at 16 weeks' gestation. Thus, under conditions of acute stress, the human fetus may produce a transient hyperglycemic response, depending on the extremely limited glycogen reserves of the fetus. When these are exhausted, hypoglycemia follows, with increases in blood lactate and blood alanine levels and in tissue hypoxia. These metabolic alterations have been documented in chronically stressed fetuses before and at birth, together with changes in gut hormones [11], erythroblastosis, and a decreased heart rate variability [12, 13]. There is additional evidence that fetal stress responses can be altered by maternal anesthesia during fetoscopy. Amniotic fluid concentrations of fetal steroid hormones were significantly decreased in fetuses whose mothers received narcotic anesthesia as compared with those who received nonnarcotic anesthesia during fetoscopy, thereby indicating the suppression of fetal stress responses by narcotic anesthetics [10].

From these data, it follows that even the very preterm neonate should be able to mount a hormonal-metabolic stress response to operations. However, the stress re-

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sponses of preterm neonates are distinctly different from those of fetuses in utero, not only because of a greater physiological maturity, but also because the epochal event of birth and the life experience of premature neonates in the days or weeks preceding surgical procedures may result in an accelerated maturation of the stress-responsive mechanisms for hormonal synthesis and metabolic regulation. The environmental or physiological triggers for initiating such changes at the cellular and molecular level are unknown; however, the gross hormonal-metabolic changes in neonates undergoing operations have been reported recently [6].

Neonatal Responses to Noncardiac Surgery

Early studies of the neonatal stress response found variable increases in blood glucose and lactate concentrations during and after operation, whereas no consistent changes occurred in the levels of urea, plasma amino acids, or free fatty acids [14, 15]. These studies concluded that anesthesia and surgery caused a short-lived metabolic disturbance in the neonate, the cause or consequence of which was unclear. Recently, however, several studies have reported hormonal changes and their metabolic effects in term neonates undergoing surgical procedures. The most prominent responses documented were massive intraoperative increases in plasma epinephrine and norepinephrine, which returned to preoperative values by 6 hours after surgery. Plasma insulin concentrations increased significantly in the postoperative period, whereas plasma glucagon had decreased by 24 hours postoperatively [16]. Although the intraoperative cortisol responses of neonates were found to have a wide variability in an earlier report [17], subsequent studies showed that term neonates mount a marked cortisol response that was maintained at 12 hours postoperatively [18].

These endocrine responses had prominent metabolic effects. Massive increases in blood glucose, lactate, and pyruvate levels occurred intraoperatively and were maintained 6 and 12 hours postoperatively. The hyperglycemic response was strongly correlated with plasma epinephrine levels at the end of operation and with plasma glucagon levels postoperatively, implying that glycogenolysis and gluconeogenesis, respectively, may be the sequential sources of glucose production during and after operation [16, 19]. Lipolysis and ketogenesis were documented by significant increases in circulating concentrations of nonesterified fatty acids (NEFA), glycerol, and ketone bodies during operation [16]. Protein breakdown in the postoperative period was documented by increased excretion of total nitrogen and increased 3-methylhistidine/creatinine ratios in the urine, together with changes in plasma amino acid levels (K. J. S. Anand and A. Aynsley-Green, unpublished observations, 1987). Although similar responses have been described following operation in adult patients, the sequence of these hormonal-metabolic changes was different. Neonatal stress responses were much greater in magnitude and shorter in duration than were those of adult patients undergoing similar procedures [6].

Responses to Cardiac Surgery

Remarkably little is known about the stress responses of neonates subjected to cardiopulmonary bypass (CPB) and deep hypothermic circulatory arrest (DHCA) associated with open-heart surgery. A recent study has demonstrated that neonatal stress responses to cardiac surgery with CPB and DHCA were characterized by marked intraoperative increases in plasma concentrations of catecholamines, endorphins, and glucagon, followed by significant insulin and glucagon responses during the postoperative period (K. J. S. Anand, P. R. Hickey, D. D. Hansen, unpublished observations, 1988). The peak norepinephrine responses at the end of circulatory arrest and peak epinephrine responses at the end of operation were found to be 3 to 10 times those of adult patients undergoing similar procedures. In contrast, modest increases in plasma endorphin values occurred intraoperatively and were not maintained postoperatively. In the postoperative period, significant epinephrine and insulin responses persisted from the end of operation to 24 hours postoperatively. Plasma glucagon increased gradually to reach significantly high values by 24 hours after operation. Blood glucose and lactate concentrations in neonates undergoing cardiac surgery increased markedly during sternotomy, with further increases during DHCA and at the end of operation. This hyperglycemia and lactic acidosis persisted for at least 12 hours postoperatively. In this study, 5 neonates died in the postoperative period and death was preceded by severe metabolic derangements that were evident several hours before death actually occurred.

Effects of Prematurity

Preterm neonates, subjected to similar anesthesia and operation as term neonates, were found to have greater catecholamine responses during and after operation (K. J. S. Anand and A. Aynsley-Green, unpublished observations, 1988). However, these differences could be related to the disparate clinical condition of neonates in the two groups, since term neonates were much more clinically stable during operation and postoperatively as compared with the premature neonates. In another study, chest physiotherapy and tracheal suctioning in ventilated preterm neonates also produced significant increases in plasma catecholamine levels [20]. Plasma insulin values increased in response to surgical hyperglycemia in term neonates, whereas no changes occurred in preterm neonates during or after operation [3]. The lack of an insulin response in preterm neonates may be due to a decreased responsiveness of beta cells in the premature pancreas [19] or may have resulted from a suppression of insulin secretion by greater catecholamine release during operation. Although Srinivasan and colleagues [21] reported no significant changes in plasma insulin values during or after operation, the wide variability in their data may have been caused by inclusion of preterm neonates, term neonates, and older infants in their study.

Perioperative changes in plasma steroid hormones were strikingly different between preterm and term neonates. Term neonates mounted a significantly greater cortisol response during and after operation, whereas preterm neonates mounted significantly greater responses of the precursor steroid hormones, such as progesterone, 17-hydroxyprogesterone, 11-deoxycorticosterone, and 11-deoxycortisol. These differences may reflect the relative maturity of steroid biosynthesis in the fetal adrenal cortex, since the maturation of hydroxylase enzymes occurs from the proximal to the distal end of the steroid biosynthetic pathway [22]. Probably for similar reasons, unstressed preterm neonates have lower plasma concentrations of cortisol and aldosterone and higher values of the precursor steroid hormones as compared with term neonates [23, 24].

The hyperglycemic responses of preterm and term neonates were similar intraoperatively but were prolonged postoperatively in the preterm neonates, probably due to the lack of an insulin response. From changes observed in circulating concentrations of plasma amino acids, it has been suggested that postoperative glucose production may result from endogenous protein breakdown and increased gluconeogenesis in preterm neonates, whereas glycogenolysis would be the most likely mechanism in term neonates (K. J. S. Anand and A. Aynsley-Green, unpublished observations, 1987). Increases in total ketone bodies during operation were observed in term neonates, but not in preterm neonates, which may be due to smaller lipid stores in preterm neonates or partially due to an incomplete development of the enzymes required for ketogenesis in the preterm liver (K. J. S. Anand and A. Aynsley-Green, unpublished observation, 1988). These metabolic differences between preterm and term neonates may produce greater tissue breakdown in preterm babies undergoing similar degrees of surgical stress.

Effects of Graded Surgical Stress

The effects of an increasing severity of operation were defined recently by a clinical scoring method designed to measure the degree of surgical stress in neonates [25]. Discriminant analysis for validation of this scoring method demonstrated its accuracy in 89% of cases. The most prominent differences among neonates undergoing minor, moderate, and severe surgical stress were seen in the epinephrine and norepinephrine responses during and after operation. Greater and more prolonged changes in plasma catecholamines may be due to an increasing degree of sympathoadrenal activation brought about by operations of increasing stress. Major differences were also observed among minor, moderate, and severe stress groups in the plasma glucagon and cortisol responses 6 hours after operation [25].

The blood concentrations of gluconeogenic substrates (lactate, pyruvate, alanine, and glycerol) provided the most prominent differences between the metabolic responses of neonates subjected to increasing degrees of surgical stress. These differences may be due to a markedly increased production of gluconeogenic substrates stimulated by catecholamine release and contributed by the glucagon and glucocorticoid responses [1]. Similarly, the magnitude of the intraoperative hyperglycemic response was correlated strongly with the degree of surgical stress. Probably resulting from reflex glucoregulation, the insulin responses of neonates undergoing minor, moderate, and severe surgical stress were significantly different at the end of operation [25]. The relationship of postoperative protein breakdown to the degree of surgical trauma was confirmed by Greenwall and colleagues [26], who reported that nitrogen loss following major surgery was much greater than that following minor surgery. Although the degree of surgical stress was related to an increasing incidence of postoperative complications and mortality [25], this relationship may depend on several factors, such as the physical status of the patient, the clinical condition for which operation was required, the anesthetic and perioperative management, and the detrimental effects of severe surgical stress per se.

Effects of Anesthetic Management

Lack of knowledge of the neonatal stress responses and development of pain perception led to the widespread practice of giving minimal or no anesthesia to newborn infants undergoing an operation [28]. An analysis of 40 published reports on preterm neonates undergoing ligation of a patent ductus arteriosus showed that anesthetic management of 77% of cases consisted of either muscle relaxants alone or muscle relaxants plus nitrous oxide [28]. In a randomized controlled trial, preterm babies undergoing patent ductus arteriosus ligation were given nitrous oxide and curare, with or without the addition of fentanyl (10 μg/kg IV) [29]. Major hormonal responses to operation, as indicated by changes in levels of plasma epinephrine, norepinephrine, glucagon, aldosterone, corticosterone, and other steroid hormones, were significantly decreased in neonates receiving fentanyl anesthesia. The massive hormonal responses of neonates receiving nitrous oxide alone were associated with significant increases in blood glucose, lactate, and pyruvate and were prevented in neonates also given fentanyl [29]. Increased endogenous protein breakdown and an increased incidence of postoperative complications after operation were also noted in the nitrous oxide anesthesia group, as compared with the fentanyl–nitrous oxide group [29].

In another randomized controlled trial, term neonates undergoing noncardiac surgery received anesthesia with nitrous oxide and curare, with or without the addition of halothane to the anesthetic regimen [30]. Neonates given halothane and nitrous oxide anesthesia showed decreased hormonal responses to operation as compared with neonates given nitrous oxide alone, with significant differences in the epinephrine, norepinephrine, and cortisol responses during and after operation. Changes in circulating concentrations of glucose, nonesterified fatty acids, and ketone bodies were also decreased in neonates receiving halothane anesthesia, together with a decreased incidence of complications during and after operation [30]. These investigations showed that lack of potent anesthesia may be partially responsible for the massive stress responses of neonates reported in earlier studies. In addition, randomized trials of halothane and fentanyl anesthesia suggested that giving potent anesthesia to neonates undergoing an operation may result in an improved clinical outcome postoperatively. These studies have not only provided a physiological rationale for the reassessment of appropriate anesthetic techniques for neonates, but have also focused attention on the larger questions of analgesia and sedation for artificial ventilation and frequent invasive procedures performed on preterm and term neonates during intensive care [31]. Similarly, the anesthetic techniques employed for older infants and children probably can be reevaluated from a detailed knowledge of their stress responses to operation and other invasive procedures.

STRESS RESPONSES IN INFANTS AND CHILDREN

Several factors may theoretically explain the observed differences between the neonatal stress responses and those of older infants and children undergoing an operation. Maturation of the cellular and molecular mechanisms controlling hormonal secretion occurs during the postnatal period. For example, by 3 months of age the fetal adrenal cortex involutes and the definitive pattern of steroid biosynthesis is established; modulation of insulin and glucagon secretion by catecholamines and by circulating glucose concentrations undergoes maturation [32, 33]. The density, distribution, and coupling of several hormone receptors may change markedly in target tissues such as the liver [34, 35]. In addition, major changes occur in the enzyme systems responsible for intermediary metabolism in liver cells and extrahepatic tissues. The rate of growth is relatively decreased in infants and children, and they have much greater stores of fat, protein, and carbohydrates in comparison to neonates. Thus, the stress responses of infants and young children are distinct from those of neonates. Another major change in the pattern of surgical stress responses occurs around puberty, leading to adult patterns of the stress response in adolescents.

Remarkably little is known about the hormonal-metabolic responses of infants and young children undergoing noncardiac surgery, whereas those undergoing cardiac surgery have been studied in much greater detail.

Responses to Noncardiac Surgery

An early study, using relatively less sensitive methods of measurement, found no significant changes in plasma epinephrine and norepinephrine values in infants undergoing bilateral hernial repair [36]. Subsequent studies found that plasma catecholamine levels increased markedly in children undergoing adenoidectomy, and these changes were associated with significant increases in plasma concentrations of adrenocorticotropic hormone (ACTH), cortisol, and other corticosteroid hormones [37]. Similar increases in plasma ACTH and cortisol were found to be associated with marked increases in plasma β-endorphin and arginine vasopressin levels in children undergoing bilateral herniorrhaphy [38]. In another study, significant increases in plasma prolactin, growth hormone, cortisol, and insulin concentrations occurred during operation, whereas the plasma levels of other pituitary hormones were unaltered [39]. Infants subjected to abdominal surgery under minimal anesthesia also showed massive changes in plasma cortisol levels at the end of the operation [17].

Perioperative metabolic changes, particularly with regard to changes in blood glucose, have been described in several reports. All these studies have documented hyperglycemic responses during operation and have attempted to relate changes in blood glucose levels to the duration of preoperative starvation or the rate of dextrose infusion during operation [40–42]. Plasma nonesterified fatty acids also increased significantly in a study of infants undergoing an operation [36]. Previous studies have reported significant increases in urinary nitrogen excretion and negative nitrogen balance postoperatively in infants and children undergoing an operation [43, 44]. These studies also found that the postoperative nitrogen loss was substantially greater in infants (<2 years of age) than in older children (2–12 years of age) undergoing similar procedures, and that nitrogen loss could be decreased by protein-calorie supplementation or by treatment with anabolic steroids in the postoperative period [43, 44].

Further detailed studies of the hormonal-metabolic changes in infants and children undergoing an operation have been investigated recently (M. P. Ward-Platt, A. Aynsley-Green, unpublished data, 1987). Infants and children (age, 1 month to 10 years) were evaluated prospectively for the degree of surgical stress [25] and received standardized anesthetic and perioperative management. These children mounted a substantial plasma cortisol response during operation that was maintained even up to 48 hours after operation. The magnitude of the acute cortisol response was similar to that of neonates undergoing surgical operations, although it was maintained much longer postoperatively. Further analysis showed that the cortisol responses of older children persisted longer into the postoperative period than did those of younger children. Unlike adult patients, the pattern of the cortisol response was unimodal, as there was no evidence of a second peak on the first postoperative day.

Plasma glucagon concentrations in children were unchanged during operation and up to 48 hours after operation. These findings were in striking contrast with neonatal and adult glucagon responses, since glucagon increases occur intraoperatively and in the early postoperative period in neonates, whereas marked glucagon increases occur in the late postoperative period in adults undergoing major surgery. Plasma insulin values increased markedly during operation in children, and significantly high levels were maintained for over 48 hours after operation. These insulin responses were also in contrast to the stress responses of neonates and adults, in whom significant changes in plasma insulin levels occurred only during the postoperative period. Consequently, in children the insulin/glucose ratio increased during and after operation, whereas this ratio decreased during operation in neonates and was unaltered in adult patients. Changes in the insulin/glucose ratio were significantly different between the younger children (<5 years of age) and older children (>5 years of age) in this study [45]. Thus, the endocrine and metabolic responses of children undergoing noncardiac surgery were quite different from patterns of the stress response observed in neonates and adult patients. Similar differences may be expected between their responses to cardiac surgery.

Responses to Cardiac Surgery

The stress responses following cardiac surgery in infants and children have been studied in greater detail than have the responses to noncardiac surgery. In infants less than 18 months of age, Firmin and colleagues [46] found that plasma catecholamine levels increased during a period of surface cooling and increased further to reach peak concentrations following DHCA. In children up to 6 years of age undergoing cardiac surgery, massive increases in plasma catecholamine levels and plasma renin activity also occurred during CPB and DHCA [47]. In children less than 8 years of age, Milne and co-workers [48] and Shida and associates [49] found no changes in plasma cortisol concentrations during cardiac surgery with CPB and DHCA, whereas a significant increase was recorded at the end of the operation. These studies also found marked intraoperative increases in plasma growth hormone, with peak concentrations at rewarming on CPB; significantly increased levels of growth hormone were maintained at 1 hour postoperatively in infants [48] and up to 24 hours postoperatively in older children [49]. Marked increases during cardiac surgery with peak values reached during CPB also occurred in the concentrations of plasma vasopressin [50] and atrial natriuretic factor [51] in infants and children undergoing open-heart surgery. Several studies have documented a suppression of insulin secretion and massive hyperglycemia in infants and children undergoing cardiac surgery with or without circulatory arrest [48, 49, 52–56]. In most cases, plasma insulin values decreased during CPB and DHCA and increased markedly in the rewarming phase. Peak values were reached either at the end of CPB or in the early postoperative period. In contrast, plasma glucagon concentrations were significantly increased on rewarming at the end of DHCA, but much greater increases occurred postoperatively, with peak values at 24 hours after operation and significantly raised values at 48 hours postoperatively [48, 49].

These major hormonal responses probably mediate the metabolic adjustments leading to massive hyperglycemia reported in metabolic studies of infants and children undergoing cardiac surgery [47–49, 52–57]. Bevan and Rosales [56] proposed that this hyperglycemic response may be due to decreased glucose utilization during CPB, although an increased rate of glucose production during operation was not excluded. Several studies have also documented increased concentrations of blood lactate during cardiac surgery, with massive increases during circulatory arrest [47, 48, 57, 58]. These responses may result from an increased rate of lactate production (caused by glycogenolysis due to the epinephrine release and an increased buildup of lactate in peripheral tissues during DHCA), which may be compounded by a decreased rate of lactate utilization by the gluconeogenic pathway in liver cells [59]. These mechanisms are associated with marked increases in the lactate/pyruvate molar ratio during CPB and, particularly during DHCA [48], an increased oxygen debt following circulatory arrest [57], and increases in blood glycerol values during CPB and DHCA [48, 59].

These stress responses were qualitatively and quantitatively different from those of adult patients undergoing cardiac surgery. In general, hormonal-metabolic changes in infants and children were greater in magnitude than those of adult patients, particularly with regard to the increases in plasma epinephrine, glucagon and growth hormone, and blood glucose and lactate levels during and after operation. Infants and children mounted uniphasic cortisol responses that were smaller than the marked biphasic responses of adult patients undergoing cardiac surgery, and plasma insulin levels decreased to lower values both during and after operation as compared with levels in adult patients. Thus, differences between the pediatric and adult stress responses may be evident following cardiac and noncardiac surgery.

Effects of Graded Surgical Stress

In the absence of more precise data, a crude assessment of the effects of increasing severity of surgical stress can be made from comparing the stress responses of pediatric patients undergoing cardiac and noncardiac surgery. Although such a comparison would show major differences between the magnitude and duration of stress responses in these two groups of patients, it would be open to errors resulting from the effects of CPB and DHCA in one group of patients; the varied characteristics, clinical condition, and management of patients in different studies; the methods used for collection and analysis of blood samples; and various other sources of systematic error. Recent studies (M. P. Ward-Platt and A. Aynsley-Green, unpublished data, 1987) have prospectively defined the degree of surgical stress in 46 infants and children undergoing noncardiac surgery, using an objective scoring method developed originally for surgical neonates [25].

These studies showed important differences between the responses of children undergoing major and minor degrees of surgical stress. Plasma cortisol responses were much greater following major surgery, with significant differences between the two groups at the end of operation and 6 hours postoperatively. Plasma concentrations of growth hormone and prolactin increased significantly during operation in both groups of children undergoing minor and major surgical stress; but these hormonal responses were not correlated with the degree of surgical stress. Although plasma glucagon responses were similar in children undergoing minor and major surgical stress, plasma insulin responses increased significantly with the degree of surgical stress [45]. Similar differences occurred with respect to the metabolic stress responses of children subjected to increasing degrees of surgical stress. Surgical procedures caused significant increases in the blood concentrations of glucose, lactate, pyruvate, NEFA, and ketone bodies, all of which were correlated significantly with the degrees of surgical stress as defined by the scoring method used [25]. Probably as a result of postoperative glucose production, blood concentrations of total gluconeogenic substrates were markedly decreased 24 hours after operation; these decreases were predicted accurately by the surgical stress scores of the children studied [45].

Effects of Anesthetic Management

Relatively few studies have compared the hormonal-metabolic stress responses of infants and children receiving different anesthetic techniques during operation; randomized controlled trials to examine these differences are even fewer. The effects of potent anesthesia on the cortisol responses of infants undergoing major abdominal surgery was investigated in a nonrandomized study. Infants given nitrous oxide and muscle relaxants mounted significantly greater cortisol responses than did infants also given halothane [17]; similar data for neonates undergoing surgery have already been described [30].

In older children undergoing adenoidectomy, Sigurdsson and co-workers [37] found that addition of morphine and scopolamine to the premedication with diazepam significantly decreased their cortisol, 17-hydroxyprogesterone, and ACTH responses and virtually abolished the catecholamine responses to operation. A subsequent randomized study showed that the plasma catecholamine responses to adenoidectomy were significantly greater during halothane anesthesia than during enflurane anesthesia [60]. These differences were obtained for both intubated and nonintubated children undergoing adenoidectomy, and the decreased catecholamine responses in the enflurane anesthesia group were associated with a decreased incidence of cardiac arrhythmias during operation [61]. In the same study, however, no significant differences occurred between the cortisol and ACTH responses of the groups receiving halothane or enflurane anesthesia [60].

In infants and children (age, 5–60 months) undergoing pelvic surgery, the hormonal stress responses during halothane–nitrous oxide anesthesia were abolished by epidural anesthesia [38]. Measurements of plasma β-endorphins, ACTH, and arginine vasopressin and blood glucose levels 5 and 15 minutes after incision were significantly different between the two anesthesia groups; subsequent measurements were not done. Plasma cortisol concentrations were unchanged in both anesthetic groups, presumably because of the short blood sampling period after the start of operation [38]. In older children undergoing major abdominal operations, epidural anesthesia was also found to prevent the intraoperative adrenocortical stress responses: no change or a significant decrease occurred in the plasma concentrations of cortisol, aldosterone, and precursor steroid hormones at the end of operation [62]. However, a rebound phenomenon, similar to that seen in adults receiving epidural anesthesia, occurred within 24 hours postoperatively, with significant increases in the adrenocortical stress hormones. The postoperative increases in plasma cortisol and aldosterone levels, at least up to 6 hours after operation, were blocked by giving etomidate infusions in addition to epidural anesthesia during operation [62]. In contrast, plasma concentrations of the precursor steroid hormones were massively increased by etomidate infusion [62], thereby suggesting that the adrenocortical suppression induced was not due to anesthesia, but was caused by a direct effect on adrenocortical cells. Much greater research will be required to define the effects of different anesthetic agents on the stress responses of infants and children undergoing an operation. More importantly, further studies are required to define the clinical correlates of modifying the pediatric stress responses by different anesthetic techniques.

CONCLUSIONS

Although the data available on stress responses of neonates and older children undergoing surgical procedures illustrate specific differences from the adult stress responses, there are distinct similarities as well. In general, the release of catabolic stress hormones during and after operation precipitates metabolic adjustments leading to the breakdown of protein, fat, and carbohydrate stores. Within physiological limits, these endocrine-metabolic changes may facilitate wound healing and recovery, but if severe or prolonged, these stress responses may precipitate postoperative complications leading to an increased morbidity and mortality. Neonatal and pediatric stress responses are relatively greater in magnitude than the adult responses to similar procedures. In addition, newborns and young children may be particularly susceptible to the detrimental effects of a severe stress response because of their inherent metabolic characteristics. Based on these considerations, the primary conclusion derived from this review is that hormonal-metabolic changes in pediatric patients undergoing an operation have not received the research attention they deserve. From the preliminary evidence presented herein, it is possible to speculate that major clinical benefits could be derived from the maintenance of metabolic homeostasis during the postoperative period. Further research is required urgently to design specific anesthetic and analgesic regimens for this purpose. Furthermore, detailed investigation of the pediatric stress responses would provide a physiological rationale to evaluate currently used anesthetic regimens, so that future anesthetic practice can be based on scientific considerations rather than on clinical empiricism.

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Measurements of plasma total and free testosterone (T) levels in human subjects from fetal to postpubertal life showed about twofold higher total T and 15-fold higher free T levels in female fetuses than in female adults. The ratios between the sexes were only moderate in fetal life. Between the 17th and 31st week of pregnancy the ratios (male:female) of total T were found to be 6.6 in week 17, 1.5 in week 22, 2.3 in week 28 and 1.2 in week 31 of pregnancy compared to 16.2 in adulthood. The corresponding ratios of free T were calculated to be 5.6 in week 17, 1.4 in week 22, 0.9 in week 28 and 0.7 in week 31 of pregnancy compared to 34 in adulthood. In amniotic fluids, we measured even an overlapping of T values between the two sexes. The reason for the observed striking difference of T levels between the sexes in fetal and postpubertal life may be the high adrenal activity and secretion rate in fetal life during brain differentiation. In rats, the contribution of adrenals to plasma T levels is only moderate and much smaller than in human beings. As measured in adult female rats, the portion was found to be about 20% only, contrary to about 60% in women. The main sources of T in female rats appear to be the gonads. The mainly gonadal secretion may be the reason that exposure of pregnant rats to stress diminished the T levels in male fetuses, but did not significantly elevate the T levels in females.(ABSTRACT TRUNCATED AT 250 WORDS)

<3>
Authors
Partsch CJ. Sippell WG. MacKenzie IZ. Aynsley-Green A.
Title
The steroid hormonal milieu of the undisturbed human fetus and mother at 16-20 weeks gestation.
Source
Journal of Clinical Endocrinology & Metabolism. 73(5):969-74, 1991 Nov.
Abstract

The interrelations of steroid hormone levels in plasma and amniotic fluid from mothers and their undisturbed fetuses at early midgestation of human pregnancy have not been defined previously. We, therefore, studied 12 healthy mothers and their fetuses undergoing termination of pregnancy for social reasons at 16-20 weeks gestation. Fetal arterial and venous blood was obtained by direct vessel puncture through a fetoscope in the conscious sedated mothers immediately before termination of pregnancy. Simultaneously, maternal peripheral venous blood and amniotic fluid were collected. Aldosterone (Aldo), corticosterone (B), 11-deoxycorticosterone, progesterone (P), 17-hydroxyprogesterone (17OHP), 11-deoxycortisol, cortisol (F), and cortisone were simultaneously determined by specific RIA after extraction and chromatography. Positive fetal arterio-venous differences were found for F, B, and Aldo, whereas arteriovenous differences were negative for P and 17OHP. In amniotic fluid, six of the eight corticosteroids showed significantly lower levels during fetoscopy than during routine amniocentesis, as reported previously using the same analytical methods. The present study demonstrates that the undisturbed human fetus at 16-20 weeks gestation actively secretes the most important gluco- and mineralocorticoids, F, B, and Aldo, independent of the mother. P and 17OHP were shown to be primarily derived from placental production and supplied to the fetus as a source of F and Aldo biosynthesis. The fetoscopy procedure with premedication seemed to give rise to less stress to the fetus than routine amniocentesis without sedation. Fetoscopy is, therefore, an ideal method to study feto-maternal steroid interrelations in human pregnancy.

<4>
Authors
Kinney HC. Ottoson CK. White WF.
Title
Three-dimensional distribution of 3H-naloxone binding to opiate receptors in the human fetal and infant brainstem.
Source
Journal of Comparative Neurology. 291(1):55-78, 1990 Jan 1.
Abstract
Despite the putative role of opioids in disorders of the developing human brainstem, little is known about the distribution and ontogeny of opioid-specific perikarya, fibers, terminals, and/or receptors in human fetuses and infants. This study provides baseline information about the quantitative distribution of opiate receptors in the human fetal and infant brainstem. Brainstem sections were analyzed from three fetuses, 19-21 weeks gestation, and seven infants, 45-68 postconceptional weeks, in whom the postmortem interval was less than or equal to 12 hours. Opiate receptors were localized by autoradiographic methods with the radiolabelled antagonist 3H-naloxone. Computer-based methods permitted quantitation of 3H-naloxone binding in specific nuclei, as well as three-dimensional reconstructions of binding patterns. High 3H-naloxone binding corresponds primarily to sensory and

limbic nuclei, and to nuclei whose functions are known to be influenced by opioids, e.g., trigeminal nucleus (pain), nucleus tractus solitarii and nucleus parabrachialis medialis (cardio-respiration), and locus coeruleus (arousal). The regional distribution of opiate receptors as determined by 3H-naloxone binding is similar in human infants to that reported in human adults and animals and corresponds most closely to that of mu receptors. We found, however, that opiate receptor binding is high in the fetal and infant inferior olive, in comparison to low binding reported in this site in adult humans, primates, and rodents. In addition, opiate receptors are sparse in the fetal and infant substantia nigra, as in reports of the adult human substantia nigra, compared to moderate densities reported in primates and rodents. By midgestation, the regional distribution of 3H-naloxone binding in human fetuses is similar, but not identical, to that in infants. Highest 3H-naloxone binding occurs in the inferior olive in fetuses at midgestation, compared to the interpeduncular nucleus in infants. Tritiated naloxone binding quantitatively decreases in virtually all nuclei sampled over the last trimester, but not to the same degree. The most substantial binding decrease (two- to fourfold) occurs in the inferior olive and may reflect programmed regressive events, e.g., neuronal loss, during its development. Definitive developmental trends in 3H-naloxone binding are not observed in the postnatal period studied. The heterogeneous distribution of opiate binding in individual brainstem nuclei underscores the need for volumetric sampling in quantitative studies.

<5>
Full Text Link Available
Authors
 Pillai M. James D.
Title
 The importance of the behavioural state in biophysical assessment of the term human fetus.
Source
 British Journal of Obstetrics & Gynaecology.
 97(12):1130-4, 1990 Dec.
Abstract
 We have examined how the different behavioural states exhibited by 78 healthy fetuses at term influence the result of the non-stress test (NST) and biophysical profile score (BPS). In association with state 1F the average recording time to obtain a satisfactory NST and BPS was 27.0 and 26.3 min respectively, and 52.6% and 44.0%

Hormone Res. *22:* 115–128 (1985)

Studies on the Hormonal Regulation of Fuel Metabolism in the Human Newborn Infant Undergoing Anaesthesia and Surgery

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Key Words. Neonates, preterm and term · Neonatal anaesthesia · Neonatal surgery · Neonatal metabolism · Stress response

Abstract. Little is known of the endocrine and metabolic milieu in preterm and term neonates exposed to surgical stress. In order to define the effects of anaesthesia and surgery on the hormonal regulation of intermediary metabolism, the levels of plasma insulin, glucagon, adrenaline and noradrenaline were measured in addition to blood glucose, lactate, pyruvate, alanine, acetoacetate, hydroxybutyrate, glycerol and plasma-free fatty acids in 38 neonates (23 term, 15 preterm) undergoing surgery. Blood samples were drawn pre-operatively, at the end of surgery, and at 6, 12 and 24 h post-operatively. Plasma levels of adrenaline and noradrenaline increased significantly in response to surgery. In term neonates, plasma insulin concentrations were unaltered at the end of surgery, but were significantly increased throughout the post-operative period; plasma glucagon levels were unchanged at the end of surgery but had significantly decreased by 24 h after surgery. Insulin levels in preterm neonates remained unchanged during surgery as well as in the post-operative period. All neonates developed a significant peri-operative hyperglycaemia which persisted up to 12 h after surgery. Blood lactate and pyruvate increased during surgery, accompanied by significant increases in plasma free fatty acids, total ketone bodies and glycerol concentrations by the end of surgery. Blood glucose concentrations were significantly correlated with plasma adrenaline levels at the end of surgery and with plasma glucagon at 6 h post-operatively. The insulin/glucose ratio was significantly decreased at the end of surgery in term and preterm neonates. Further analysis showed that total parenteral nutrition given just before surgery and thiopentone anaesthesia given during surgery significantly augmented the peri-operative hyperglycaemic response of term neonates.

Thus, stress-related hormonal changes in preterm and term neonates may precipitate a catabolic state characterized by glycogenolysis, gluconeogenesis, lipolysis and mobilization of gluconeogenic substrates in the post-operative period. Prevention of these metabolic derangements by anaesthetic or hormonal manipulation may possibly help to improve the clinical outcome of neonates undergoing surgery.

Introduction

In adult patients undergoing surgery, marked alterations in fuel homeostasis have been documented as a result of stress-related hormonal changes. Thus, the release of cortisol, catecholamines, glucagon and growth hormone during and after surgery, combined with the suppression of insulin secretion [1, 2] may trigger a cascade of metabolic adjustments resulting in post-operative catabolism and substrate mobilization. The most prominent feature of peri-operative metabolic change is a significant hyperglycaemia which is caused by hepatic and peripheral glycogenolysis, the mobilization of gluconeogenic substrates such as lactate, pyruvate, alanine and glycerol, together with a decreased peripheral utilization of glucose. This endocrine-metabolic response is not entirely beneficial and may precipitate a number of undesirable effects [3, 4] including an increased morbidity and mortality in high-risk adult patients [3, 5].

Although the human newborn infant, particularly when born prematurely, is considered to be ill equipped to meet such metabolic demands, remarkably little is known of neonatal metabolic regulation during anaesthesia and surgery. The normal neonate exists in a precarious metabolic milieu and experiences a number of major hormonal and metabolic changes as it adapts to the post-natal environment and to post-natal nutrition [6]. Moreover, the infant's body reserves of carbohydrate, fat and protein are limited [7] at a time when it has to meet the metabolic cost of rapid growth and organ maturation [8]. From all this, it follows that a severe and prolonged catabolic reaction to surgery experienced by seriously ill or premature neonates may lead to severe, if not life-threatening, metabolic complications. From published reports of post-operative outcome, it is evident that a higher post-operative morbidity occurs in the neonatal age group than is seen in older children or adults subjected to similar surgical procedures [9–13]. Moreover, a number of postoperative complications have been documented in neonates undergoing surgery, such as, severe weight loss, persistent metabolic acidosis, cardiorespiratory instability, gastric stress ulcers, the hyperosmolarity syndrome and negative nitrogen balance; which may have contributed *ipso facto* to the morbidity and mortality following neonatal surgery [12–16].

In order to help resolve some of these clinical problems and to try to improve present management we have designed a study to define the hormonal response and metabolic adjustments of preterm and term newborn infants subjected to anaesthesia and surgery.

Methods

After approval by the Hospital Ethics Committee and having obtained written parental consent, 38 neonates undergoing surgery (23 term and 15 preterm) were included in this study. Infants born small-for-gestational age and neonates suspected to have congenital metabolic or hormonal abnormalities were excluded. None of the infants had been exposed to major stress in the form of severe asphyxia, hypothermia, trauma or haemorrhage within the 72 h preceding surgery. The mean age, gestation and weight at the time of operation of the neonates are listed in table 1.

Blood samples were drawn immediately before the induction of anaesthesia, at the end of surgery, and at 6, 12 and 24 h following surgery. Blood levels of glucose, lactate, pyruvate, alanine, free fatty acids, hydroxybutyrate, acetoacetate and glycerol were measured by specific enzymatic methods [17], radioimmunoassay methods were used to measure plasma levels of insulin [18] and glucagon [19]; adrenaline and noradrenaline were measured by a double-isotope radio-enzymatic assay [20].

The infants were premedicated with atropine (0.02–0.04 mg/kg) alone. Anaesthetic agents were limited to the use of thiopentone, halothane *d*-tubocurarine and nitrous oxide. No opiates were given before or during surgery. Intravenous fluids were adjusted to administer dextrose at a standard infusion rate of 3–7 mg/kg/min [21]. Following surgery, analgesia was provided by intramuscular injections of morphine given as indicated by medical staff but its administration was adjusted so that the drug was not injected in the 3 h preceding a post-operative blood sample.

The extent of operative stress experienced by each patient was calculated by using a scoring method based on factors that contribute to the stress of surgical trauma together with others specific for neonatal patients [64]. According to this score, the magnitude of surgical stress was minor (score 0–5) in 10 patients, moderate (score 6–10) in 24 patients and severe (score 11–20) in 4 patients.

The results were analyzed by non-parametric statistical tests. Wilcoxon's test was used to test changes after surgery in relation to pre-operative values, differences between groups were tested by the means of the Mann-Whitney U test and correlation between parameters was established by the Spearman rank correlation coefficient [22]. The region of rejection for the null hypothesis was fixed at $\alpha = 0.05$. For the sake of clarity the results are expressed as mean ± SEM.

Results

Term Neonates

The overall results of hormonal and metabolic analysis in term neonates are listed in table II. There was a significant increase in plasma adrenaline $p < 0.005$) and noradrenaline ($p < 0.025$) concentrations at the end of surgery, but by 6 h post-operatively the levels had returned to pre-operative values. Plasma insulin levels did not change during surgery, but by 6 h following surgery a significant increase had occurred ($p < 0.025$) which was maintained up to 24 h post-operatively ($p < 0.025$). There was no significant alteration in plasma glucagon levels during or soon after surgery; however, by 24 h post-operatively a significant decrease had occurred ($p < 0.025$) from the pre-operative value. Blood glucose concentrations increased significantly ($p < 0.005$) from a mean pre-operative value of 4.8 ± 0.4 mmol/l to 9.9 ± 0.8 mmol/l at the end of surgery, and remained elevated at 6 h ($p < 0.05$) and 12 h ($p < 0.005$) after surgery. There was a significant increase in blood concentrations of lactate ($p < 0.005$), pyruvate ($p < 0.005$), glycerol ($p < 0.025$), total ketone bodies (acetoacetate and hydroxybutyrate) ($p < 0.025$) and plasma free fatty acids ($p < 0.025$) by the end of surgery. Levels of blood lactate and pyruvate remained significantly elevated for more than 12 h post-operatively, whereas all other metabolites reverted to pre-operative levels by 6 h after surgery. Blood alanine concentration did not change during or after surgery.

Preterm Neonates

The results of hormonal and metabolic analysis in preterm neonates are listed in table III. Plasma concentrations of adrenaline and noradrenaline were found to increase significantly during surgery ($p < 0.05$ and $p < 0.005$, respectively) and returned to

Table I

	Term neonates	Preterm neonates
Number of patients	23	15
Gestation, weeks	38.2 ± 0.4	29.0 ± 1.0
Age at operation, days	15 ± 2	34 ± 3
Weight at operation, kg	3.0 ± 0.1	1.4 ± 0.2

Table II. Term neonates

	n	Pre-op	End-op	6 h post-op	12 h post-op	24 h post-op
Hormones						
Adrenaline, nmol/l	10	0.4 ± 0.1	2.4 ± 1.0***	0.5 ± 0.2	–	0.5 ± 0.2
Noradrenaline, nmol/l	10	5.9 ± 1.7	8.7 ± 2.2**	7.0 ± 2.0	–	5.2 ± 1.0
Insulin, pmol/l	21	75 ± 13	101 ± 21	154 ± 32**	131 ± 20**	181 ± 38**
Glucagon, pmol/l	7	29 ± 6	31 ± 7	23 ± 5	17 ± 5	16 ± 5**
Metabolites						
Glucose, mmol/l	21	4.8 ± 0.4	9.9 ± 0.8***	5.7 ± 0.7*	6.1 ± 0.8***	5.1 ± 0.3
Lactate, mmol/l	21	1.6 ± 0.1	2.8 ± 0.3***	2.3 ± 0.3**	2.0 ± 0.2***	2.1 ± 0.2
Pyruvate, mmol/l	21	0.09 ± 0.01	0.15 ± 0.01***	0.13 ± 0.01**	0.11 ± 0.01*	0.11 ± 0.01
Alanine, mmol/l	21	0.25 ± 0.02	0.28 ± 0.02	0.27 ± 0.02	0.25 ± 0.02	0.25 ± 0.02
FFA, mmol/l	6	0.38 ± 0.10	0.63 ± 0.07**	0.51 ± 0.17	0.35 ± 0.08	0.27 ± 0.04
Glycerol, mmol/l	21	0.15 ± 0.01	0.20 ± 0.02**	0.16 ± 0.01	0.18 ± 0.02	0.16 ± 0.02
Total ketones, mmol/l	21	0.24 ± 0.07	0.35 ± 0.10**	0.26 ± 0.11	0.19 ± 0.08	0.20 ± 0.04

Wilcoxon's test from pre-operative values: * $p < 0.05$; ** $p < 0.025$; *** $p < 0.005$.

Table III. Preterm neonates

	n	Pre-op	End-op	6 h post-op	12 h post-op	24 h post-op
Hormones						
Adrenaline, nmol/l	8	1.2 ± 0.4	2.2 ± 0.7*	1.5 ± 0.9	1.3 ± 0.8	0.8 ± 0.4
Noradrenaline, nmol/l	8	6.3 ± 0.8	15.9 ± 3.0***	8.3 ± 2.7	8.2 ± 2.3	6.2 ± 1.5
Insulin, pmol/l	8	134 ± 53	83 ± 20	103 ± 25	69 ± 7	100 ± 39
Metabolites						
Glucose, mmol/l	15	5.8 ± 0.6	12.2 ± 1.5***	9.3 ± 1.8**	8.0 ± 1.2**	7.8 ± 1.3
Lactate, mmol/l	15	1.5 ± 0.1	2.3 ± 0.3***	1.4 ± 0.2	1.3 ± 0.2	1.5 ± 0.2
Pyruvate, mmol/l	15	0.11 ± 0.01	0.14 ± 0.02**	0.11 ± 0.01	0.11 ± 0.01	0.12 ± 0.02
Alanine, mmol/l	15	0.16 ± 0.02	0.15 ± 0.03	0.15 ± 0.02	0.15 ± 0.02	0.15 ± 0.02
Glycerol, mmol/l	15	0.17 ± 0.02	0.24 ± 0.04**	0.16 ± 0.02	0.17 ± 0.03	0.17 ± 0.03
Total ketones, mmol/l	15	0.16 ± 0.03	0.28 ± 0.08***	0.18 ± 0.03	0.17 ± 0.04	0.16 ± 0.04

Wilcoxon's test from pre-operative values: * $p < 0.05$; ** $p < 0.025$; *** $p < 0.005$.

pre-operative levels by 6 h after surgery. The concentration of plasma insulin did not change significantly during surgery and stayed low throughout the postoperative period. Blood glucose concentrations increased significantly ($p < 0.005$) from a pre-operative level of 5.8 ± 0.6 mmol/l to 12.2 ± 1.5 mmol/l at the end of surgery and remained significantly elevated at 6 h ($p < 0.025$) and 12 h ($p < 0.025$) after surgery.

There was also a significant rise in the blood levels of lactate ($p < 0.005$), pyruvate ($p < 0.025$, total ketone bodies (acetoacetate and hydroxybutyrate) ($p < 0.025$) and glycerol ($p < 0.005$) by the end of the operative procedure, but by 6 h post-operatively the levels of all these metabolites had reverted to their pre-operative values. There was no significant change in blood alanine concentration during or after surgery.

Endocrine-Metabolic Correlations

Due to constraints on the volume of blood sampling, hormonal measurements were not performed on all patients. Therefore, hormonal-metabolic correlations were derived from those data of preterm and term neonates in which hormonal and metabolic variables had been measured on the same blood sample. Blood glucose concentrations were strongly correlated with plasma adrenaline values (fig. 1) at the end of surgery ($r_s = 0.69$, $n = 17$, $p < 0.005$) and with plasma glucagon at 6 h post-operatively ($r_s = 0.86$, $n = 7$, $p < 0.05$). Levels of blood lactate were correlated with plasma adrenaline concentrations (fig. 1) at the end of surgery ($r_s = 0.66$, $n = 17$, $p < 0.005$) and 6 h after surgery ($r_s = 0.70$, $n = 14$, $p < 0.005$). A significant correlation was also present between blood glycerol levels and plasma adrenaline ($r_s = 0.76$, $n = 17$, $p < 0.005$) and noradrenaline ($r_s = 0.69$, $n = 17$, $p < 0.005$) at the end of surgery. The insulin/glucose molar ratio (fig. 2) decreased significantly at the end of surgery ($p < 0.005$) in preterm and term neonates. In the post-operative period, however, the insulin/glucose ratio was significantly raised in term neonates at 6 h ($p < 0.05$), 12 h ($p < 0.025$) and 24 h ($p < 0.05$) after surgery, whereas it remained below the pre-operative value in preterm neonates ($p < 0.05$).

Effects of Anaesthetic Management

In the group of term neonates undergoing moderate surgical stress, 6 neonates received an anaesthetic regimen of halothane (1–2% for induction, 0.5% for maintenance), nitrous oxide (50%), *d*-tubocurarine and oxygen; and another 5 neonates received thiopentone (4–5 mg/kg for induction, 1–2 mg/kg supplement if surgery lasted over 1 h), nitrous oxide (50%), *d*-tubocurarine and oxygen. The results from these groups were therefore compared.

The post-operative hyperglycemic response of the neonates who received thiopentone anaesthesia was significantly greater than that of neonates who received halothane anaesthesia ($p < 0.025$). There were no significant differences between the two groups in the blood levels of lactate, pyruvate, alanine, total ketones and glycerol before or after surgery. Moreover, no significant difference was found in the plasma insulin levels of the two groups peri-operatively (fig. 3).

Effects of Total Parenteral Nutrition

In the early part of this study, two term neonates who had undergone relatively minor surgical procedures were found to develop an inappropriate degree of hyperglycaemia at the end of surgery which was much greater than the response of 6 other neonates subjected to similar surgical procedures (fig. 4). On comparison of the peri-operative management of these neonates, it was found that both neonates with an abnormal hyperglycaemic response had received parenteral nutrition solutions containing amino acids and soluble fats up to just before the induction of anaesthesia. Mean plasma glucagon concentrations from both these neonates were found to be 55 and 70 pmol/l before and after surgery whereas the mean glucagon con-

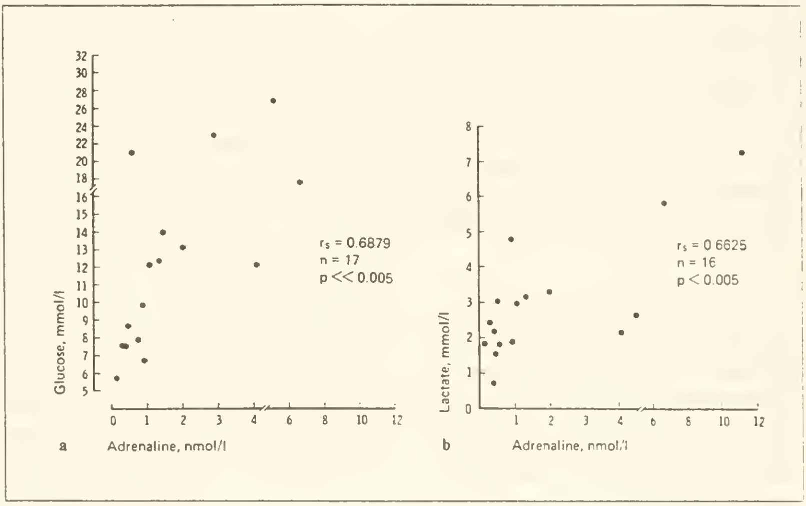

Fig. 1. Correlation of plasma adrenaline values with (a) blood glucose and (b) blood lactate levels at the end of surgery. r_s = Spearman rank correlation coefficient.

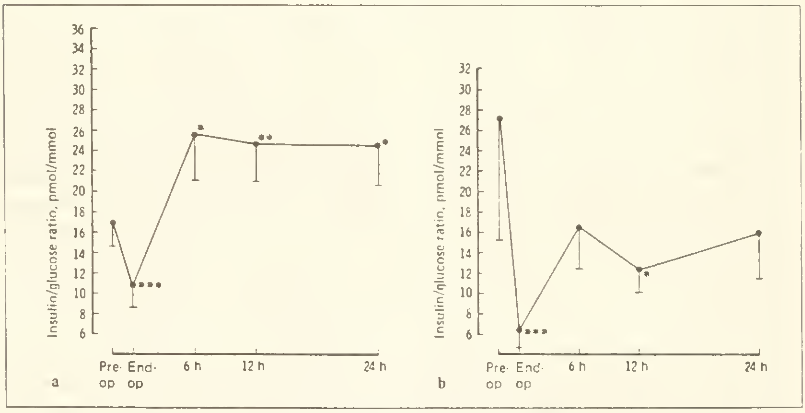

Fig. 2. Insulin/glucose ratio in (a) term and (b) preterm neonates undergoing surgery. Wilcoxon's test from pre-operative values: * $p < 0.05$. ** $p < 0.025$. *** $p < 0.005$.

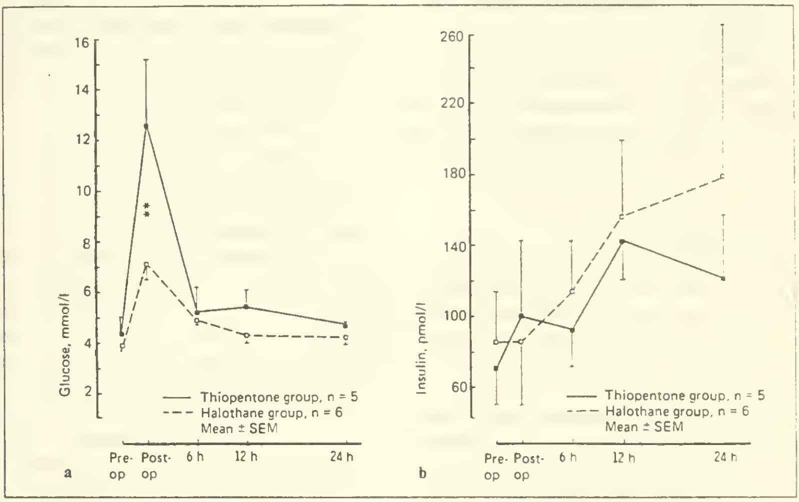

Fig. 3. Comparison of changes in (a) blood glucose and (b) plasma insulin between neonates anaesthetized with thiopentone or halothane. Mann-Whitney U test: ** $p < 0.025$.

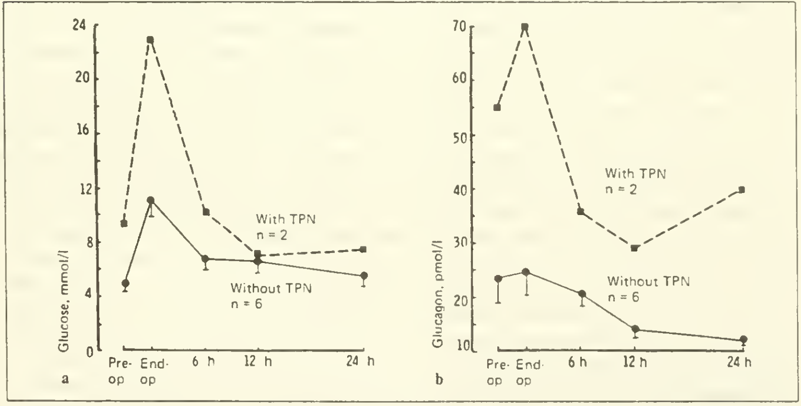

Fig. 4. Comparison of changes in (a) blood glucose and (b) plasma glucagon between term neonates with or without receiving TPN pre-operatively.

centrations in other term neonates were 23 and 26 pmol/l, respectively.

Subsequently, the data from both these neonates were excluded from further analysis and total parenteral nutrition solutions were not given to neonates undergoing surgery from 6 h pre-operatively upto 24 h after surgery.

Discussion

The hormonal regulation of intermediary metabolism in preterm and term human neonates undergoing anaesthesia and surgery has not been studied before. Apart from studies of electrolyte excretion and nitrogen balance [23–32], the limited data available from the literature relate only to the measurement of metabolic parameters in term neonates subjected to surgery. In studies which can be criticized on methodological grounds; *Elphick* [33], *Elphick and Wilkinson* [34] and *Pinter* [36, 37] showed that blood glucose levels increased during surgery and remained elevated, in some cases, for up to 8 h after surgery, even though glucose clearance rates were not altered post-operatively [35]. No consistent changes occurred in the levels of urea, plasma amino acids [37], or free fatty acids [34, 37]. *Elphick and Wilkinson* [34] found that triglycerides decreased post-operatively whereas other neutral lipids were unaltered and *Pinter* [37, 38] documented an increasing acidaemia during the operative procedure which was directly correlated to blood lactate levels. From all these studies, it was concluded that anaesthesia and surgery caused a short-lasting metabolic disturbance in the human neonate [33–39], the cause or consequence of which was unclear [34, 37]. Despite variable amounts of surgical stress in the neonates studied, the poorly controlled anaesthetic techniques and peri-operative management, and the lack of standardization of blood sampling or analytical methods, these studies represent the only previous attempts to define the metabolic response of newborn infants to surgical trauma.

In this study, various factors which could affect the peri-operative metabolic milieu were standardized for all neonates investigated. The duration of pre-operative starvation was limited to 4 h, fluid therapy was adjusted in order to deliver dextrose at a rate of 3–7 mg/kg/min [21], parenteral nutrition solutions containing amino acids or soluble fats were not given from 6 h pre-operatively until 24 h after surgery; neonates were protected as much as possible from heat loss during transfer to the theatre as well as during anaesthetic induction and the surgical procedure, and lastly, the timing of post-operative analgesia was adjusted so as to have no effect on the hormonal or metabolic variables measured in this study.

In term as well as preterm neonates, the stress stimuli during anaesthesia and surgery caused a substantial increase in the plasma levels of adrenaline and noradrenaline. The pattern of change in noradrenaline levels was similar to that of adult patients [2], but the increase in adrenaline levels during surgery contrasts with the data available from adult subjects in whom adrenaline levels may fall or remain unchanged during surgery, and rise only during the post-operative period [2].

Previous studies in term neonates have documented that there is a marked release of catecholamines at the time of birth [40–42] which may be augmented in infants undergoing fetal distress [40, 41], birth asphyxia [41], or breech deliveries, and in infants of diabetic mothers [43]. Using a fluorometric technique for measurement of catecholamines. *Lagercrantz and Bistoletti* [41] have shown that preterm neonates have smaller catecholamine responses than term infants to the process of birth as well as to birth asphyxia. In our study, however, preterm neonates were found to have higher adrenaline levels before and after surgery and higher noradrenaline levels at the end of surgery and in the post-operative period (table II, III). It is well-known that the sympathoadrenal system is functional from very early fetal life [44] and it is possible that the life experience of preterm neonates over the 2 or 3 weeks before surgery may result in a maturation of the stress-responsive pathways for catecholamine production and release. The higher catecholamine levels before and after surgery in preterm neonates may be explained by the fact that most of them required artificial ventilation before and after surgery and were clinically less stable than the term neonates.

Insulin concentrations did not change significantly by the end of surgery in preterm or term neonates. In term neonates plasma insulin levels were significantly raised at 6, 12 and 24 h post-operatively, a pattern of change which is somewhat similar to that of adult patients. In contrast to adult subjects and term neonates, insulin levels in preterm neonates remained unchanged during the post-operative period. This finding, the clinical importance of which is explained below, may possibly be due to a decreased responsiveness of beta-cells in the premature pancreas [45] and may explain the tendency of preterm neonates to develop a greater hyperglycaemia than term neonates during and after surgery (table III). Glucagon concentrations, which were measured only in term neonates, had decreased significantly from pre-operative levels by 24 h after surgery. This is in striking contrast to the adult stress response, where a marked increase in glucagon levels has been documented between 12 and 24 h post-operatively [2]. However, since glucagon levels have been measured in only a small number of patients (n = 7) this finding needs to be confirmed in subsequent studies.

The most important metabolic effect we have documented is the post-operative hyperglycaemia which was invariably present in all neonates studied. The mechanism of post-operative hyperglycaemia can be considered in relation to the concurrent changes in insulin and the counter-regulatory hormones [46]. At the end of surgery, the good correlation between blood glucose and plasma adrenaline values (fig. 1) implies that the hyperglycaemic response may be precipitated by adrenaline release during surgery. 6 h post-operatively, blood glucose concentrations were only poorly related to adrenaline levels, but were closely related to plasma glucagon, a correlation which achieved statistical significance even though glucagon was measured in only a few patients. According to these data therefore, it may be proposed that post-surgical hyperglycaemia in neonates is initiated by adrenaline release and is maintained into the early post-operative period as a result of glucagon secretion. Adrenaline not only stimulates hepatic glucose production [47] and causes a sustained decrease in peripheral glucose utilization [49, 50], it also stimulates glucagon secretion and suppresses the release of insulin [48, 51]. In this milieu, glucagon secretion may further stimulate hepatic glucose production [47, 51, 52] and therefore, the hyperglycaemic response may be potentiated or prolonged. Of greater importance however, is the lack of insulin secretion in response to the hyperglycaemia developed during surgery, which is probably due to a direct inhibition of insulin secretion by intra-operative adrenaline release [48, 49]. Consequently, the insulin/glucose molar ratio decreased significantly at the end of surgery in term neonates as well as preterm neonates, reflecting inappropriately low insulin levels for the circulating glucose concentrations (fig. 2). During the post-operative period, however, the insulin/glucose ratio increased significantly in the term neonates, whereas it remained low in the preterm neonates. The total lack of insulin response in preterm neonates may not only result in unopposed catabolism during the post-operative period, but through the development of a greater hyperglycaemia, may precipitate a rapid increase in plasma osmolality during surgery.

The substantial hyperglycaemic response, particularly in neonates undergoing severe surgical stress, has important clinical implications due to its effect on plasma osmolality [53]. In newborn infants, an increase in plasma osmolality of greater than 25 mosm/kg H_2O over a period of 4 h [54] can have detrimental effects on the renal cortex and cerebral substance and may even lead to intraventricular haemorrhage [54, 55]. The deleterious effects of a hyperosmolar state are of even greater potential significance in preterm neonates.

Concurrent with post-operative hyperglycaemia significant increases in blood lactate and pyruvate concentrations were seen at the end of surgery in term as well as preterm neonates. These metabolites remained elevated in term neonates up to 12 h after surgery, but had decreased to pre-operative levels in preterm neonates by 6 h post-operatively. Levels of blood lactate and plasma adrenaline were significantly correlated at the end of surgery and 6 h post-operatively. Arteriovenous catheterization studies in adult patients have shown that the release of adrenaline during surgery causes an increased production of lactate and pyruvate through glycogenolysis in skeletal muscles [56]. In addition, it is well known that injured tissues around the surgical wound derive their energy mainly from glycolysis [57] and thus may contribute towards increased lactate production after surgery. The greater degree and duration of hyperlactataemia in term neonates may possibly be related to the presence of greater glycogen stores in their skeletal muscles, particularly in comparison to preterm infants. As shown by double-isotope turnover studies in normal neonates [21], these metabolites are removed from the circulation by the liver to be used as substrates for hepatic gluconeogenesis [47, 52] and thus may contribute towards the post-operative hyperglycaemia [2, 57].

The significant increase in free fatty acids, glycerol and total ketone bodies during surgery is indicative of lipolysis and ketogenesis mediated by intra-operative catecholamine release [58]. Evidence for catecholamine-dependent lipolysis is further provided by the strong correlation of blood glycerol concentrations with plasma adrenaline and noradrenaline levels at the end of surgery. Studies of glycerol turnover in newborn infants have shown that 75% of glycerol thus formed enters the gluconeogenic pathway in the neonatal liver and contributes to 5% of hepatic glucose production [59]. The oxidation of free fatty acids in the neonatal liver may further stimulate post-operative gluconeogenesis by the generation of extra ATP to support gluconeogenesis, the production of acetyl-CoA which activates pyruvate carboxylase, and the provision of reducing equivalents for glyceraldehyde-3-phosphate dehydrogenase [60]. The metabolism of ketone bodies in peripheral tissues, through the formation of citrate and inhibition of phosphofructokinase, may inhibit the peripheral utilization of glucose and further contribute towards post-operative hyperglycaemia in neonates [58].

Effects of Anaesthetic Management

The only significant difference between neonates anaesthetized with thiopentone and halothane was a greater hyperglycaemia at the end of surgery in infants who were given thiopentone. This effect was short-lasting and by 6 h after surgery blood glucose levels in both groups were similar again (fig. 3). Since there was no difference in the insulin levels of both groups (fig. 3), it is possible that this was a direct effect of thiopentone on glucose metabolism. Similar results have been reported in adult patients undergoing surgery [61] and it has been shown that thiopentone activates hepatic glycogen phosphorylase [62], and thus may result in further stimulation of hepatic glycogenolysis during surgery.

Effects of Parenteral Nutrition

Two term neonates arrived in the anaesthetic room while receiving parenteral nutrition solutions continuously. They were changed to 4% dextrose – 0.18% saline, anaesthesia was given and a simple gastrostomy was performed on both of them. After surgery, they remained on dextrose-saline infusion as per the study protocol. Both neonates were found to develop a much greater hyperglycaemia at the end of surgery as compared to 6 other neonates undergoing similar surgical procedures, and also had markedly raised glucagon levels before and after surgery (fig. 4). The hyperglycaemic effect of parenteral nutrition per se has been documented [63] and it is well known that amino acids provide a potent stimulus for the secretion of glucagon [51].

Conclusions

From this study it is evident that the human neonate, whether born prematurely or at full term, is entirely capable of mounting an endocrine and metabolic stress response to surgical trauma. The main features of this response are the release of catecholamines and the inhibition of insulin secretion during surgery. Post-operative adjustments in fuel homeostasis result in the development of a substantial and prolonged hyperglycaemia, together with increases in the blood levels of lactate, pyruvate, free fatty acids, glycerol and ketone bodies (acetoacetate and hydroxybutyrate).

This study has documented distinct differences between preterm and term neonates, in the pattern and magnitude of insulin secretion and catecholamine release, thereby resulting in an altered control of glucose homeostasis in the post-operative period. It has also shown that parenteral nutrition solutions given pre-operatively and thiopentone anaesthesia given during surgery may significantly affect glucoregulation in the surgical neonate.

The information has important implications for current neonatal anaesthetic practices [64] as well as the clinical management of preterm and term neonates before and after surgery. Since post-traumatic morbidity and mortality in high-risk adults have been related to metabolic parameters of the stress response [3–5], specific anaesthetic techniques [65–68] and hormonal therapy [69, 70] have been used in order to inhibit the stress response of adult subjects undergoing major surgery. It is presently not known whether prevention of the metabolic derangements by anaesthetic or hormonal manipulation in preterm or term neonates will lead to a decrease in post-operative complications and an improvement of post-surgical morbidity and mortality.

Further detailed studies are needed to define more precisely the effects of other surgical, anaesthetic and analgesic circumstances. Turnover studies using stable isotopes are required to investigate the pathways responsible for these metabolic changes. Furthermore, the physiological mechanisms responsible for the initiation and modulation of the neonatal stress response may need to be defined. Such data will help to develop specific regimens for preterm and term neonates exposed to various stress situations and thus may lead to an improved clinical outcome.

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Measuring the Severity of Surgical Stress in Newborn Infants

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● Measurement of the severity of surgery would greatly facilitate the design and interpretation of studies in neonates undergoing surgery. A scoring method, based on the amount of blood loss, superficial dissection, and visceral trauma, the site and duration of surgery, cardiac surgical factors, and associated stress factors for surgical neonates, was formulated and applied to 94 neonates undergoing surgery. Perioperative management was standardized for all patients and hormonal-metabolic variables were measured in blood samples drawn preoperatively at the end of the operation, and at six, 12, and 24 hours after operation. The stress scores were correlated significantly with the plasma epinephrine ($P < .0001$), norepinephrine ($P < .0001$), insulin ($P < .001$), glucagon ($P < .005$), and cortisol ($P < .02$) responses, and with changes in blood glucose ($P < .0001$), lactate ($P < .0001$), pyruvate ($P < .0001$), and alanine ($P < .005$) during and after operation. Discriminant function analysis was used for further validation and this scoring method was found to predict accurately the severity of surgical stress in 89.4% cases. Discrepancies in the remaining cases were found to be related to specific clinical factors. On comparison of the hormonal and metabolic responses of neonates in the minor (N = 71), moderate (N = 12), and severe (N = 11) stress groups, increasing severity of surgical stress was found to be associated with greater and more prolonged changes in plasma catecholamines, blood glucose, and gluconeogenic substrates during and after operation. Clinical outcome following operation was also significantly different between the three stress groups. Thus, the hormonal and metabolic responses of neonates undergoing operation are directly proportional to the degree of surgical stress as defined by the proposed scoring method.
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INDEX WORDS: Neonatal surgical stress.

INTERPRETATION of research in the field in neonatal surgery has been complicated by the marked variability in patient characteristics and clinical presentation of the conditions that require surgical intervention in this age group. It is essential to take these differences into account when comparing postoperative outcome in different groups of neonates operated either in the same center or in different centers,[1] when comparing the physiologic effects of changes in clinical therapy, or when evaluating the postoperative requirements for intensive care or hospital stay. However, no convenient method has been available to allow the categorization of severity of surgical stress in the human neonate.

As part of a larger project to define the neonatal stress responses to surgery and anesthesia,[2] we designed a scoring method specifically for the assessment of surgical stress in newborn infants; the structure of this system was based on the results of studies on the stress response in adult patients.[3] The objectives of this report are, first, to validate the proposed method by correlating the scores with the hormonal and metabolic responses of neonates undergoing surgery, and second, to characterize the neonatal responses to different degrees of surgical stress.

MATERIALS AND METHODS

Development of a Scoring Method for Surgical Stress

The scoring method was based on the five factors that contribute to the stress of surgical trauma: the amount of blood loss, the degree of superficial dissection, the extent of visceral trauma, and the duration of operation (Table 1). Specificity for neonatal patients was obtained by the addition of "associated stress factors" to this basic framework. The value judgements required for assigning scores to each variable were arbitrary, but were based on published studies of the surgical stress response in adults and on the advice of pediatric, anesthetic, and surgical colleagues.[2]

Components of the Stress Score

(1) The amount of blood loss was graded in the light of data from the study of surgical hemorrhage in 1,787 pediatric patients by Davenport and Barr, which showed that 10% blood volume was lost

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Table 1. Scoring Method for Surgical Stress

	Score
1. Amount of blood loss	
<5% blood volume	0
5% to 10% blood volume	1
10% to 15% blood volume	2
>15% blood volume	3
2 Site of surgery	
Superficial	0
Intraabdominal/intracranial	1
Intrathoracic	2
3 Amount of superficial trauma (skin, muscle etc)	
Minimal	1
Moderate	2
Maximal	3
4 Extent of visceral trauma	
Brief visceral handling	1
Prolonged visceral handling	2
Minor resection	3
Major resection	4
5 Duration of surgery	
0-30 min	1
30-90 min	2
90-180 min	3
180-300 min	4
>300 min	5
6 Associated stress factors	
(a) Hypothermia 1.5° to 3°C	1
Hypothermia >3°C	2
Deep hypothermia	3
(b) Localized infection	1
Generalized infection (NEC, septicemia etc)	3
(c) Prematurity	
30 to 34 wk	1
<30 wk	2
7 Cardiac surgery	
Cardiopulmonary bypass	4
Circulatory arrest	
<40 min	2
>40 min	4

Note For patients undergoing cardiopulmonary bypass, scores for amount of blood loss are applied to the blood loss before the start of bypass

Scoring procedure 1-10, minor surgical stress 11-10, moderate surgical stress, 21-30, severe surgical stress

during minor operations, 10% to 15% during moderate operations and more than 15% during severe operations

(2) The site of surgery was established as an important factor from the stress responses[3] and clinical outcome[4] of adult patients undergoing surgery. These differences depend probably on handling and trauma of the peritoneum, pleura, periosteum, or dura, or the physiologic stress associated with operating in the body cavities

(3) The amount of superficial dissection was given a score on the basis of an empirical judgment of the surgeon It was reasoned that immediately after an operation most surgeons would be able to make an accurate assessment of the amount of tissue dissection required and that only slight discrepancies may be expected between different surgeons

(4) The visceral trauma was graded as a separate variable because the handling or resection of body viscera strongly stimulates the stress response[3,5,6] a reflex mediated via the autonomic fibers supplying the adrenal cortex, adrenal medulla, sympathetic ganglia, pancreas, and liver

(5) From studies in adult patients, the duration of operation was established as an important determinant of surgical stress This factor may be of greater importance for neonates due to their limited metabolic reserves and the policy of minimal anesthesia that is advocated currently for them[7]

(6) The selection of associated stress factors was considered necessary, in order to account for the stress response of special groups of patients, particularly premature neonates, those exposed to hypothermia during surgery, or those with localized or generalized infections preoperative[2,6]

(7) In neonates undergoing cardiac surgery, factors such as cardiopulmonary bypass (CPB), deep hypothermia, and duration of circulatory arrest were also graded, since studies in adult patients established that these procedures were very potent stimuli for the stress response[3,10]

Scoring procedure The total scores were used to classify the degrees of surgical stress as minor (score 1 to 10), moderate (score 11 to 20), and severe (score 21 to 30)

Clinical Material and Analytical Methods

After approval of the project by the Hospital Ethics Committee and after parental consent, 94 newborn infants (61 term and 33 preterm) were evaluated and scored by a member of the surgical team immediately after operation. Thus, 71 neonates were subjected to minor surgical stress, 12 neonates to moderate stress, and 11 neonates to severe stress Small-for-gestational age neonates neonates with congenital metabolic or hormonal abnormalities, or neonates exposed to hypoxemia, hypothermia, trauma, or hemorrhage within the 72 hours preceding surgery were not studied All infants were premedicated by atropine alone, anesthetic agents were limited to the the use of halothane, thiopentone, fentanyl, and nitrous oxide Perioperative intravenous fluids were adjusted to infuse dextrose at a rate of 3 to 7 mg/kg/min

Blood samples were obtained preoperatively, at the end of operation and at six, 12, and 24 hours following operation Blood concentrations of glucose, lactate, pyruvate, alanine, nonesterified fatty acids, glycerol, 3-hydroxybutyrate, and acetoacetate were measured by enzymatic methods[11]; radioimmunoassay methods were used to measure plasma concentrations of insulin,[12] glucagon,[13] and cortisol[14]; plasma epinephrine and norepinephrine were measured by a double-isotope radioenzymatic assay[15]

Statistical Analyses

Initial validation of this scoring method was obtained by correlating perioperative hormonal and metabolic changes to the total stress score obtained by each neonate using the Spearman rank correlation coefficient (r_s)[16]

Further validation was obtained by predicting the group membership of each neonate on the basis of its hormonal and metabolic response Initially, the data from 48 neonates were selected randomly and subjected to discriminant analysis in order to identify those parameters that produced the greatest discrimination between the three stress groups Using the discriminant function coefficients of these parameters, discriminant scores were calculated from the data of each patient and were used to predict the stress groups of all 94 neonates[17] The degree of congruence between the stress groups originally allotted to the neonates and those predicted from their stress response was taken as an objective measure of the validity of this scoring method

Finally, differences in the hormonal-metabolic responses of neonates from the three stress groups were tested by Kruskal-Wallis analysis of variance.[16]

RESULTS

Correlation of Stress Scores With Hormonal and Metabolic Changes

The stress scores were correlated strongly with the changes in plasma epinephrine concentrations at the end of operation ($P < .0001$) and at six ($P < .0001$), 12 ($P < .001$), and 24 hours ($P < .05$) postoperatively, and with plasma norepinephrine responses at the end of operation ($P < .0001$), at six ($P < .05$) and 12 hours ($P < .025$) after operation. In addition, the stress scores were correlated with plasma insulin responses during operation ($P < .001$) and glucagon responses at six ($P < .005$) and 12 hours ($P < .005$) following operation; plasma cortisol responses were correlated with the stress scores at six ($P < .05$) and 24 hours ($P < .025$) postoperatively (Table 2).

With regard to the metabolic responses (Table 3), stress scores were found to be correlated strongly with the changes in blood glucose ($P < .0001$), lactate ($P < .0001$), pyruvate ($P < .0001$), and alanine ($P < .005$) concentrations at the end of operation. Thereafter, significant correlations were obtained with the changes in blood lactate at six ($P < .0001$) and 12 hours ($P < .01$) after operation; with blood pyruvate changes at six ($P < .0001$), 12 ($P < .0001$), and 24 hours ($P < .005$) postoperatively, and with blood alanine changes at the end of the operation ($P < .005$) and at six hours after operation ($P < .005$). As expected from these data, the stress scores were also correlated with changes in total gluconeogenic substrates (sum of the blood concentrations of lactate, pyruvate, alanine, and glycerol) at the end of operation ($P < .0001$), and six ($P < .0001$) and 12 hours ($P < .01$) postoperatively.

Discriminant Analysis and Prediction of Stress Groups

In an initial analysis, half the number of cases were selected randomly from each of the surgical stress groups (36 of 71 neonates from the minor stress group, 6 of 12 from the moderate group, and 6 of 11 from the severe group) and their hormonal-metabolic data were subjected to multivariate discriminate analysis with the simultaneous entry of all variables.[17] The hormonal-metabolic parameters that produced the greatest discrimination between the three stress groups were changes in plasma epinephrine, norepinephrine and insulin, blood glucose, lactate, pyruvate, alanine, and total gluconeogenic substrates at the end of operation; and changes in plasma epinephrine and glucagon, blood lactate, pyruvate, and total gluconeogenic substrates at 6 hours postoperatively. Of these, the five most important variables and their discriminant function coefficients (A1, A2, . . . A5 and B1, B2. . . B5) are listed in Table 4. There was no loss of discriminant function on discarding the other variables identified in

Table 2. Correlation Between Scores Obtained and Hormonal Chenges

	Postoperative	Six Hours Postoperative	12 Hours Postoperative	24 Hours Postoperative
Δ Norepinephrine (nmol/L)				
r_s	0.50	0.55	0.46	0.24
N	62	53	45	52
$P<$	0.0001	0.0001	0.001	0.05
Δ Epinephrine (nmol/L)				
r_s	0.43	0.25	0.27	
N	66	56	53	
$P<$	0.0001	0.05	0.025	
Δ Insulin (pmol/L)				
r_s	0.33			
N	83			
$P<$	0.001			
Δ Glucagon (pmol/L)				
r_s		0.43	0.49	
N		41	34	
$P<$		0.005	0.005	
Δ Cortisol (nmol/L)				
r_s		0.28		0.34
N		42		39
$P<$		0.05		0.02

Spearman rank correlation coefficients (r_s) showing relationships between the stress score of each patient and the change in plasma hormone concentrations after surgery. Only significant correlations shown

Table 3. Correlation Between Scores Obtained and Metabolic Changes

	Postoperative	Six Hours Postoperative	12 Hours Postoperative	24 Hours Postoperative
Δ Glucose (mmol/L)				
r_s	0.45			
N	91			
$P<$	0.0001			
Δ Lactate (mmol/L)				
r_s	0.60	0.44	0.28	
N	91	77	77	
$P<$	0.0001	0.0001	0.01	
Δ Pyruvate (mmol/L)				
r_s	0.54	0.48	0.38	0.30
N	90	79	76	77
$P<$	0.0001	0.0001	0.0001	0.005
Δ Alanine (mmol/L)				
r_s	0.28	0.33		−0.23
N	91	79		78
$P<$	0.005	0.005		0.02
Δ Total Gluconeogenic substrates (mmol/L)				
r_s	0.59	0.45	0.28	
N	90	77	75	
$P<$	0.0001	0.0001	0.01	

Spearman rank correlation coefficients (r_s) showing relationships between the stress score of each patient and the change in blood metabolite concentrations after surgery. Only significant correlations shown.

the initial analysis; thus, further analyses were performed using these five variables only.

The discriminant function coefficients listed in Table 4 were used to calculate discriminant scores from the data of each patient by the following equations:

Discriminant score

$$A = C1.A1 + C2.A2 + \ldots C5.A5$$

Discriminant score

$$B = C1.B1 + C2.B2 + \ldots C5.B5$$

where C1, C2, ... C5 were the corresponding values of the selected variables for each patient. These discriminant scores were used to place each patient within a two-dimensional discriminant function "territory," thus predicting the highest probability stress group for each neonate (Fig 1).

Table 4. Stress Score. Discriminant Analysis

Variables	Standardized Canonical Discriminant Function Coefficients	
	Function A	Function B
Δ Glucose, end-operative	0.112	0.384
Δ Total gluconeogenic substrates end-operative	0.795	−0.004
Δ Total gluconeogenic substrates six hours postoperative	0.121	0.794
Δ Epinephrine end-operative	−0.111	−1.852
Δ Epinephrine six hours postoperative	0.571	0.986

Discriminant function coefficients calculated from the data of 48 randomly selected patients. These coefficients were used for calculating the discriminant scores from the data of each patient, which were used for predicting the stress group of that patient.

Since the discriminant coefficients were calculated from the data of only half the number of neonates selected randomly, the degree of congruence between the predicted groups for all 94 neonates and the actual groups allotted to them by their total stress scores was taken as an objective measure of the validity of this scoring method. Thus, it was found that 84 neonates (89.4%) had been classified correctly by this method.

Of the ten incorrectly classified cases, eight neonates were predicted to belong to a lower stress group and two neonates were predicted to a higher stress group than had been allotted to them. The postoperative course of the former eight neonates was uneventful, whereas that of the latter two neonates was associated with severe complications in the postoperative period: (Case 1) B.N. was a one-day-old male infant operated for repair of congenital diaphragmatic hernia. Five hours after surgery he developed a pneumothorax, followed by severe hypoxia and cardiac arrest which were treated successfully. (Case 2) M.V. was a three-day-old male infant operated for meconium ileus and suspected peritonitis. The postoperative course was complicated by persistent hiccups, frequent spontaneous bradycardias, metabolic acidosis, and poor peripheral perfusion. It is likely that the postoperative course of these neonates may have influenced their

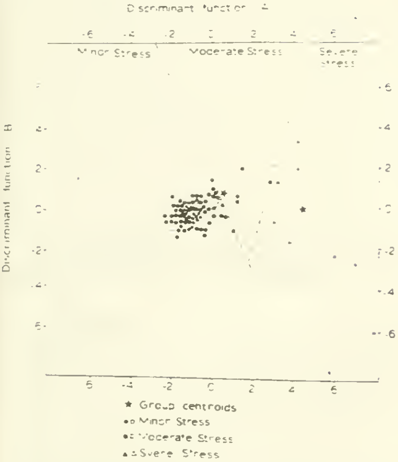

Fig 1. **Territorial distribution of all 94 neonates according to their discriminant scores calculated from the discriminant function coefficients listed in Table 4. The filled symbols represent correctly classified cases end line symbols represent incorrectly classified cases; 89.4% cases were correctly classified according to their stress scores.**

stress responses, thereby resulting in predictions to a lower or higher stress group.

Differences in Hormonal-Metabolic Responses of the Stress Groups

No significant differences were found between the minor (N = 71), moderate (N = 12), and severe (N = 11) stress groups with respect to gestation, postnatal age, and weight at the time of operation, duration of preoperative starvation, perioperative dextrose infusion rates, or the anesthetic management (Table 5).

Highly significant differences were found between the three stress groups with respect to plasma epinephrine responses at the end of operation ($P < .0001$), and at six ($P < .0001$), 12 ($P < .001$), and 24 hours ($P < .001$) after operation. Plasma norepinephrine responses were significantly different between the three stress groups at the end of operation ($P < .001$) and at six hours postoperatively ($P < .005$); Fig 2). In addition, plasma insulin responses at the end of operation ($P < .001$) and plasma glucagon responses at six hours postoperatively ($P < .005$) were significantly different between the three stress groups (Fig 3).

With regard to the metabolic changes, significant differences were found in the hyperglycemic responses of the three groups at the end of operation ($P < .005$, Fig 4). Also, the changes in blood lactate, pyruvate, alanine, and glycerol were significantly different between the three stress groups at the end of operation ($P < .0001$) and at six ($P < .001$) and 12 hours ($P < .01$) postoperatively (Fig 5).

Clinical Outcome

The postoperative recovery of neonates undergoing minor surgical stress was found to be uneventful, whereas a variety of clinical complications were documented after moderate or severe surgical stress. In addition, there were no postoperative deaths in the group undergoing minor surgical stress, whereas mortality of 17% and 36% was documented after moderate and severe surgical stress, respectively (Fig 6).

DISCUSSION

In their classic monograph "The Metabolic Response to Surgery," Moore and Ball (1952) proposed that surgical or other forms of trauma could be classified by making a semiquantitative "surgical guess" of its severity.[18] Although several studies have documented that the stress responses of adult patients subjected to different surgical procedures are significantly different, an objective method for grading surgical trauma has not been available.

Therefore, previous comparisons of the severity of surgical stress in different groups of adult patients

Table 5. Comparison of Neonates Undergoing Minor, Moderate, and Severe Surgical Stress

Patient Characteristics	Minor Stress	Moderate Stress	Severe Stress
Stress score			
Range	3-10	11-20	25-30
Mean ± SEM	6.9 ± 0.3	13.3 ± 0.9	26.8 ± 0.4
Sex	44M, 27F	7M, 5F	8M, 3F
Age (d)	19 ± 2	12 ± 4	21 ± 4
Gestation (wk)	35.8 ± 0.7	37.0 ± 1.2	38.1 ± 0.7
Weight (kg)	2.4 ± 0.2	2.7 ± 0.4	3.2 ± 0.6
Starvation, preoperative (hr)	5.6 ± 0.3	6.5 ± 0.4	6.2 ± 0.5
Intravenous dextrose, (mg/kg/min)	5.1 ± 0.2	5.1 ± 0.6	4.7 ± 0.8

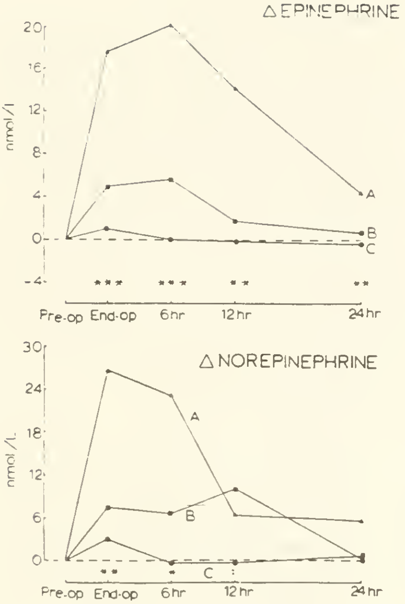

Fig 2 Differences between the plasma epinephrine and norepinephrine responses of neonates undergoing severe (A), moderate (B), and minor (C) surgical stress. Kruskal-Wallis analysis of variance: *** *P* .0001, ** *P* .001, * *P* .005.

were based on the site of operation, its duration, or other empirical considerations.[3] These studies, and the considerations detailed in the methods section above formed the basis for allotting relative "stress" values to each of the factors in this scoring method.[2] Further, the selection of "associated stress factors" for newborn infants was based on their clinical importance in modifying the overall stress associated with a surgical procedure. In this analysis, perioperative changes in hormonal and metabolic variables were used to investigate whether or not this scoring method was capable of measuring the overall stress associated with surgery.

Correlation With Hormonal and Metabolic Changes

The strong and highly significant correlations of the stress scores with changes in plasma epinephrine and norepinephrine at the end of operation and in the postoperative period defined the ability of newborn infants to recognize and respond to changes in the magnitude of surgical stress. Changes in plasma catecholamines have long been accepted as sensitive and accurate markers of physiologic stress and have a well-defined role in initiation and mediation of the metabolic responses to surgery.[19,20]

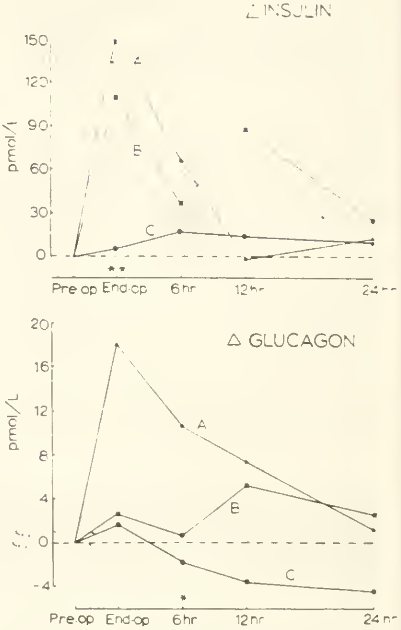

Fig 3. Differences between the plasma insulin and glucagon responses of neonates undergoing severe (A), moderate (B), and minor (C) surgical stress. Kruskal-Wallis analysis of variance: ** *P* .001, * *P*.005

The correlation of postoperative plasma glucagon responses with the stress scores may denote the stimulatory effect of epinephrine release on glucagon secretion,[3,20] whereas the correlation of stress scores with plasma insulin responses at the end of operation was probably due to a reflex insulin secretion stimulated by the hyperglycemic stress response. Although the epinephrine release during operation may suppress insulin secretion,[3,20] this effect can be overcome by a strong glycemic stimulus.[20,21] On the other hand, the poor correlation of stress scores with plasma cortisol changes is difficult to explain but may reflect impaired corticosteroid secretion from the fetal adrenal cortex in newborn infants. Hydroxylase enzymes in the fetal adrenal cortex mature from the proximal to the distal end of the steroid biosynthetic pathway[22]; therefore, the neonatal stress responses may be characterized by

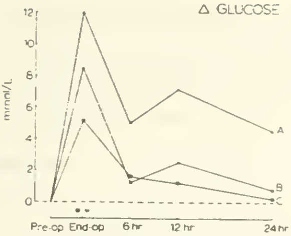

Fig 4. Differences between the hyperglycemic responses of neonates undergoing severe (A), moderate (B), and minor (C) surgical stress. Kruskal-Wallis analysis of variance: ** *P* .005.

a relatively decreased secretion of the final products of steroid biosynthesis,[23] thus resulting in a poor correlation of cortisol changes with the stress scores.

The strong correlation of stress scores with blood glucose changes during operation was expected, since hyperglycemia has been reported previously as the most prominent feature of the neonatal stress response.[7,24,25] Significant changes in the gluconeogenic substrates have also been documented previously,[7,23-25] thereby accounting for the correlations of these substrates with the stress scores (Table 3).

Thus, it was evident that the hormonal-metabolic responses of newborn infants were correlated strongly with the stress scores obtained. These correlations further implied that clinically realistic gradations of the neonatal stress response may exist even within the stress groups identified by this scoring method.

Discriminant Analysis and Further Validation

The method of discriminant analysis for validation of predictive and diagnostic indices has been used widely in the clinical sciences since it closely simulates the process of clinical decision making[26] and it summarizes complex and multivariate data into a small number of the most important variables that make a substantial contribution to the differences being examined.

For the initial analysis, half the number of neonates were selected randomly from each of the stress groups and it was found that the changes in plasma epinephrine, blood glucose, and gluconeogenic substrates at the end of surgery and at 6 hours postoperatively produced the greatest discrimination between the three stress groups. This finding appears logically correct, since epinephrine release, hyperglycemia, and substrate mobilization are salient features of the neonatal stress response.[7,23-25]

In a subsequent analysis, the highest probability stress groups were predicted for all 94 neonates in this study and were found to be congruent with the original classification in 89.4% of cases (Fig 1). This degree of congruence may be accepted as reasonable evidence for the efficacy of this scoring method. Of the ten incorrectly classified cases, the two neonates who were predicted to a higher stress group than had been allotted to them were found to have developed major postoperative complications. Since two of the variables used for discriminant analysis were measured at six hours postoperatively, these values may have been responsible for their prediction to a higher stress group. The eight neonates classified to a lower stress group showed no special characteristics except that they had undergone elective surgery and had a stable postoperative course. It is tempting to suggest that these neonates had an inherent tendency (possibly genetic) to mount a smaller stress response in relation to the degree of surgical stress experienced by them. Based on these results, it was considered justifiable to classify neonates into the subgroups defined by this scoring method and to compare their hormonal and metabolic responses for investigation of the effects of surgical stress.

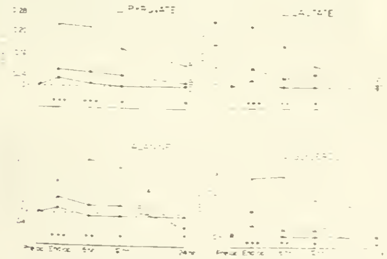

Fig 5. Differences between the metabolic responses of neonates undergoing minor (A), moderate (B), and severe (C) surgical stress. Kruskal-Wallis analysis of variance. *** *P* .0001, ** *P* .001, * *P* .01.

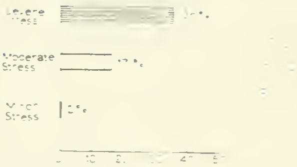

Fig 6. Differences between the postoperative mortality of neonates undergoing severe, moderate, and minor surgical stress.

Neonatal Stress Responses to Different Degrees of Surgical Stress

Apart from the effects of anesthesia, prematurity, and other factors that may influence neonatal stress responses,[2] it is reasonable to expect that the severity of surgical stress would be the most important determinant of the hormonal and metabolic changes following surgery. Also, variables that show the greatest magnitude of change would be the ones most likely to differentiate between newborn infants undergoing different grades of surgical stress.

The significant differences between the epinephrine and norepinephrine responses of neonates in the three stress groups may be due to a greater degree of sympathoadrenal activation by operations of increasing magnitude.[3] Similar differences were observed in the plasma glucagon and cortisol responses at six hours after surgery, suggesting that peak changes in these hormones may occur postoperatively rather than at the end of operation. Differences in the insulin response were observed at the end of operation and probably resulted from the surgical hyperglycemia in neonates subjected to minor, moderate, or severe surgical stress.[20,21]

Nevertheless, in the final analysis it was clear that changes in the blood concentrations of gluconeogenic substrates provided the most prominent differences between newborn infants subjected to an increasing magnitude of surgical stress. These differences may be due to the increased production of gluconeogenic substrates that may be stimulated by epinephrine release and contributed by the glucagon and glucocorticoid responses.[3,23-25] Other possible mechanisms for these changes would be a decreased utilization of gluconeogenic substrates caused either by inhibition of gluconeogenesis or due to a decreased hepatic blood flow. In a previous study as well, blood lactate values at 12 hours after surgery were significantly higher in neonates undergoing operations on the alimentary tract as compared with those undergoing nonalimentary surgery.[25] Although this difference was not commented on, it is likely that this finding was due to a greater degree of surgical stress in the former group of neonates.

The association of an increased postoperative morbidity and mortality following severe surgical stress would be expected and may be affected either by the clinical condition for which operation was required, by the poor physical status of the patient, or by the effects of severe stress per se. It is therefore emphasized that differences in the postoperative mortality of the three stress groups cannot be generalized to other patients undergoing surgical stress. These results do not imply that the scoring method for surgical stress can be used for the prediction of "surgical risk" in newborn infants. However, a large prospective epidemiologic study has been started recently in order to investigate further the relationship between surgical stress and clinical outcome.

In its present form, the main application of this scoring method would be to rationalize the homogeneity of patient material in studies of newborn infants undergoing surgery. This may be necessary for comparing different groups of neonates in the same center or in different centers, particularly when the effects of changes in perioperative management or surgical approach are under investigation. Furthermore, this scoring method could also be adapted for older children or adult patients by the inclusion of other "associated stress factors" or by combination with other clinical indices, such as the American Society of Anesthesiology (ASA) physical status,[27] the cardiac risk index,[28] or the clinical assessment scale for adult surgical patients.[29]

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cially if dissection of the coronary vessel is likely. Before this procedure is applied widely, however, the caveats regarding its use must be kept in mind. One-year follow-up data and improved techniques are just around the corner. In the meantime, physicians must select patients for this procedure judiciously and must fully inform them and their families about its associated risks and uncertainties.

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SOUNDING BOARD

PAIN, HURT, AND HARM

The Ethics of Pain Control in Infants and Children

It has long been recognized that patients receive less relief from pain than they should.[1,2] A recent review concluded that pain can be relieved effectively in 90 percent of patients but is not relieved effectively in 80 percent of patients.[3] The tendency toward undermedication for pain is even more pronounced in children than in adults.[4] There are large discrepancies between the amounts of postoperative analgesia ordered for and administered to adults and those ordered for and administered to children who have the same diagnoses and have undergone the same procedures.[5,6]

Interest in pain control in children has blossomed over the past decade, but there remains an incongruity between what is available technologically and what is practiced clinically.[7] Possible reasons for this disparity include incorrect assumptions about pain and its management, individual and social attitudes toward pain, the complexity of assessing pain in children, and inadequate research and training.[5] In each of these areas, one must ask whether the apparent undertreatment of pain in children is ethically justifiable.

The fundamental principle of responsible medical care is not "do not hurt" but "do no harm." Harm occurs when the amount of hurt or suffering is greater than necessary to achieve the intended benefit. Here lies the basic ethical challenge to care givers: Since pain seems harmful to patients, and care givers are categorically committed to preventing harm to their patients, not using all the available means of relieving pain must be justified. Possible justifications can be divided into three types: revisionist, comparative, and pragmatic.

THE REVISIONIST JUSTIFICATION

Usually, medical decision making relies on objective data. Pain is a subjective experience, however, and a direct quantitative assessment of it is difficult. Therefore, physicians rely on behavioral observations and knowledge of the specific pathophysiologic processes involved, as well as patients' own reports, to make judgments about children's experience of pain.[8] The fact that pain is undertreated in children suggests that the final assessment tends to minimize the level of pain.[9]

One possible reason for this tendency is the mistaken notion that there is a "correct" amount of pain.[10] The error results from the assumption that there is (or should be) a uniform response to a given pathophysiologic condition or pain stimulus. Despite studies showing the individual nature of children's experience of pain,[11,12] many care givers continue to ignore the individual child and provide treatment based on their idea of the "appropriate" child.[13]

Adults are often considered more reliable in reporting children's pain than are children. The concern that children may feign or exaggerate suffering to obtain some secondary gain may cause adults to discount there remains some level of risk. In this instance, parents (and patients) should be informed of the potential risk, however small, associated with opioid administration, as well as the possible advantages of adequately controlled pain over uncontrolled pain (earlier mobilization, deeper breathing, less potential for atelectasis, and less suffering).

Finally, concern about addiction causes substantial apprehension about the administration of analgesics. Survey data indicate that 39 percent of physicians are concerned about the risk of addiction resulting from the use of narcotic analgesics in young patients,[36] and this concern may be reinforced by parents' objections to giving narcotics to their children.[37] It is essential to distinguish between physical dependence (a physiologically determined state in which symptoms of withdrawal would occur if the medication were not administered) and addiction (a psychological obsession with the drug). Addiction to narcotics is rare among adults treated for disease-related pain and appears to depend more on psychosocial factors than on the disease or medically prescribed administration of narcotics.[17] Studies of children treated for pain associated with sickle cell disease[38,39] or postoperative recovery[40] have found virtually no risk of addiction associated with the administration of narcotics. There are no known physiologic or psychological characteristics of children that make them more vulnerable to addiction than adults.

An overestimation of the risk of analgesic-induced addiction leads to an underestimation of the harm of untreated pain. When analgesics are administered properly, the risk of addiction is minimal. As Angell declared, "I can't think of any other area in medicine in which such an extravagant concern for side effects so drastically limits treatment. We are used to a closer balance between risks and benefits."[10] In summary, any comparative justification for withholding pain relief must be rigorously judged on the basis of the comparative risks and benefits and empirical data, not speculation or undocumented lore.

THE PRAGMATIC JUSTIFICATION

The comparative justification recognizes that pain is bad but concludes that it is not as bad as the risks associated with the relief of pain. The pragmatic justification acknowledges that unrelieved pain is bad but asserts that such pain may be necessary to achieve a greater goal. Pain may be seen as useful to monitor an illness. For example, the patient's response to palpation of the abdomen may be an important aid in diagnosis. Pain may also indicate the ineffectiveness or limits of treatment, such as discomfort during rehabilitation after orthopedic surgery. Masking such pain could obscure physical signs and actually harm the patient. One must therefore weigh the benefit of immediate relief against that of long-term recovery.

Another goal, character development, is based on a moral view that champions traits such as courage, self-discipline, independence, and self-sacrifice. Although in principle encouraging such virtues may be ethically defensible, imposing the burden of character development on a child already encumbered by sickness and suffering reflects a lack of compassion and is ethically questionable, at best. When the total eradication of pain is not possible (as in the case of chronic pain associated with chronic illness), strengthening the child's capacity to cope with the pain is beneficial and may be justifiable. However, to withhold analgesics from a suffering child in the hope of influencing character development ignores the child's real, present need for relief from pain.

The ethical responsibility of clinicians is to provide full treatment of pain in children unless otherwise justified by defined therapeutic benefits. Three specific tests should be applied. First, is the pain useful? Is it the means to achieving an important goal? Second, is the pain necessary? Are there other, less hurtful means of achieving that goal? Third, is the pain at the lowest possible level? If there is a therapeutic benefit from a child's pain, one must be exquisitely economical with it.

CONCLUSIONS

There are now published guidelines for the management of pain in children, which are based on recent data.[41-44] However, guidelines and continuing medical education do not necessarily alter physicians' behavior.[45,46] Specific administrative interventions are required. For example, hospitals may include standards for the assessment and management of pain as part of their quality-assurance programs.[47] The Joint Commission on Accreditation of Healthcare Organizations has established standards for pain management.[48] To meet such standards, multidisciplinary teams must develop specific treatment protocols with the goal of reducing children's pain and distress. In addition, pressure from parents and the legal community is likely to affect clinical practice.

All health professionals should provide care that reflects the technological growth of the field. The assessment and treatment of pain in children are important parts of pediatric practice, and failure to provide adequate control of pain amounts to substandard and unethical medical practice.

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Fetal plasma cortisol and β-endorphin response to intrauterine needling

Xenophon Giannakoulopoulos, Waldo Sepulveda, Ploutarchos Kourtis, Vivette Glover, Nicholas M Fisk

Summary

The purpose of this study was to investigate whether the fetus mounts a hormonal stress response to a potentially painful procedure, intrauterine needling.

Cortisol and β-endorphin concentrations in fetal plasma obtained during uncomplicated fetal blood sampling or intrauterine transfusions by needling the fetal intra-abdominal portion of the umbilical vein (intrahepatic vein) were compared to hormone concentrations in fetal plasma obtained by the conventional technique of needling the placental cord insertion, which is not innervated. Cortisol and β-endorphin concentrations did not increase within 10 minutes of fetal abdominal needling ($n=15$). However, more prolonged needling during transfusion at the intrahepatic vein was associated with an increase in fetal plasma cortisol (median increase 48 nmol/L; 95% CI, 23–86) and β-endorphin (207 pg/mL; 113–307) concentrations compared to transfusion at the placental cord insertion ($p<0.005$ for both hormones). The magnitude of rise in hormone increased linearly with the duration of needling (cortisol, $r=0.80$; β-endorphin, $r=0.88$, $p<0.05$ for both).

These data suggest that the fetus mounts a hormonal stress response to invasive procedures. They raise the possibility that the human fetus feels pain in utero; and may benefit from anaesthesia or analgesia for invasive procedures.

Lancet 1994, **344**: 77–81

See *Commentary* page 72

Introduction

Until recently, the neonate was thought not to experience pain, and thus not need anaesthesia or analgesia for surgical procedures. Due largely to the research of Anand and co-workers, there is now evidence that neonates have hormonal stress responses to surgical interventions, which can be prevented by anaesthesia.[1-3] Pain relief for neonates has since been recommended[4,5] and is now standard practice in neonatal medicine and surgery.

However, interventions on the fetus are carried out without anaesthesia or analgesia. Interventions range from diagnostic needling to tissue biopsy and shunt insertion. Although the nervous pathways and neurochemical systems involved in pain perception are well developed by the third trimester, it is not known whether the fetus mounts a hormonal stress response to direct external stimuli.

The standard technique of fetal blood sampling involves needling the umbilical vein at the placental cord insertion.[6] An alternative technique, needling the umbilical vein or one of its connections (usually referred to as the intrahepatic vein[7,8]) within the fetal abdomen, is used when the approach to the placental cord insertion is difficult or hazardous (figure 1).[8,9] The intrahepatic vein is surrounded by neither cord nor arteries and, theoretically, is safer than fetal blood sampling at the placental cord insertion, which may be complicated by cord tamponade or umbilical arterial spasm.[10] In our experience, fetal blood sampling and intravascular transfusion at the intrahepatic vein does not lead to such immediate procedure-related complications,[8,9] and is used in approximately half of the fetal blood samplings in our unit. We have observed that the fetus reacts to intrahepatic vein needling with vigorous body and breathing movements, which are not present during placental cord insertion needling.

In this study we investigated whether the fetus has a hormonal stress response to direct intrauterine needling. Our hypothesis was that puncturing the fetal abdomen, as during fetal blood sampling and transfusion at the intrahepatic vein, would produce a rise in fetal cortisol and β-endorphin, but that puncturing the fetal cord during similar procedures at the placental cord insertion, which is not innervated,[11] would not.

Methods

Women with singleton pregnancies undergoing clinically indicated fetal blood sampling between 20–34 weeks of gestation at the Centre for Fetal Care, Queen Charlotte's and Chelsea Hospital, London, UK, were eligible to participate in the study if the size of the fetus was appropriate for gestational age, structurally normal on ultrasound, had end-diastolic frequencies present in the umbilical artery, and no evidence of hydrops before the procedure

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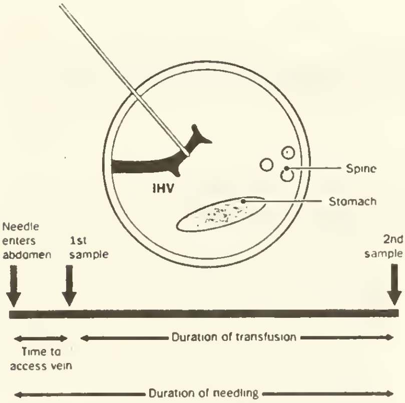

Figure 1: **Diagrammatic cross-sectional view of the fetal abdomen showing the intrahepatic vein (IHV)**

The site of ultrasound-guided fetal blood sampling was chosen as per routine clinical practice by the operator on the basis of technical factors and ease of approach. Neither maternal premedication nor fetal neuromuscular blockade was used. Randomisation of the site of sampling was not considered appropriate as anatomical factors often dictate one approach in favour of the other. After confirming the purity of fetal samples, full blood count (Coulter Counter, Coulter Electronics, Luton, UK), and blood gas analysis (Radiometer ABL 330, Copenhagen, Denmark) were done on all clinical samples. Fetuses with hypoxia, aneuploidy, or severe anaemia (Hb < 5 g/dL) were excluded, as were fetuses with bradycardia, since these conditions could be associated with basal elevations in the study endpoints.[12,13] Procedures that were complicated or involved multiple fetal vessel punctures were also excluded.

46 fetuses who satisfied these criteria were studied prospectively from June, 1992, to October, 1993, during which time 187 fetal blood sampling procedures were done. Indications for fetal blood sampling were rapid karyotyping (19), evalulation of fetal anaemia (12), or treatment by intravascular transfusion in alloimmunised pregnancies (15). After collection of clinical samples, 1·5–3·0 mL of additional venous blood was withdrawn for purposes of this study and a further sample collected on completion of intravascular transfusion. All women signed written informed consent to the collection of additional samples for research purposes, as approval by the institutional ethics committee.

We examined the effect of fetal intrauterine needling by comparing plasma cortisol and β-endorphin concentrations in fetuses undergoing fetal blood sampling at the intrahepatic vein (15) with those at the placental cord insertion (16). Although fetal blood sampling at the intrahepatic vein is more difficult, and it usually takes longer to gain access to the fetal circulation than sampling at the placental cord insertion, it was anticipated that the duration of uncomplicated fetal blood sampling at the intrahepatic vein (≤ 10 minutes) might not be sufficient in which to detect a rise in circulating fetal cortisol and β-endorphin.

The only ethically acceptable means by which delayed fetal samples could be obtained was in alloimmunised fetuses undergoing intravascular transfusion. We therefore determined whether fetal blood sampling at the intrahepatic vein evokes a hormonal stress response by comparing hormone concentrations in fetal venous samples collected before and after transfusion. We controlled for any confounding effects of transfusion by comparing procedures at the intrahepatic vein (9) with those at the placental cord insertion (6). To determine whether the magnitude of the stress response varies with the duration of the stimulus, we investigated its relation to the time from the needle entering the abdomen to collecting the first sample; the length of time the needle was in the fetal vein; and the time from the needle entering the fetal abdomen to collecting the last sample (figure 1).

Total cortisol was determined in plasma by radioimmunoassay (RIA) with a commercial kit (DPC, Los Angeles, USA). Intra-assay and inter-assay coefficients of variation were 5% at 20 nmol/L and < 10% at 1400 nmol/L. The lower limit of sensitivity was 10 nmol/L. Each individual fetus' plasma samples were determined in the same assay run. β-endorphin was determined with a combination of a previously described high-performance liquid chromatographic (HPLC) technique to allow separation of β-endorphin from β-lipotropin,[14] and highly sensitive RIA. The HPLC-eluted β-endorphin was freeze-dried and assayed with a kit employing disequilibrium kinetics (Peninsula Labs Inc, Belmont, USA). Assay sensitivity was 5 pg/mL. Overall recovery was 92% (SD 5%), according to tests with ^{3}H- and ^{125}I-β-endorphin. Intra-assay and inter-assay coefficients of variation for the whole assay were 8·1% and 9·5%, respectively. All β-endorphin specimens were analysed in the same assay run.

As basal values for both hormones were normally distributed, unpaired *t*-testing was used to compare values at the two sites. Blood gases (pO_2, pCO_2) were expressed as gestation-independent *z*-scores.[15] All other parameters were analysed by the Mann-Whitney test for between-group and Wilcoxon test for within-

	Fetal blood sampling only			
	Placental cord insertion		Intrahepatic vein	
Number	15		16	
Gestational age (weeks)	31 (23–34)		27 (23–29)	
pO_2 (*z* scores)	0·1 (−0·5 to 0·5)		0·1 (−0·5 to 0·5)	
pCO_2 (*z* scores)	0·1 (−0·6 to 0·5)		−0·1 (−0·5 to 0·4)	
pH	7·39 (7·37–7·42)		7·39 (7·36–7·41)	
Cortisol (nmol/L)	36 (28–45)		34 (27–39)	
β-endorphin (pg/mL)	61 (49–73)		55 (39–71)	
	Transfusion			
	Placental cord insertion		Intrahepatic vein	
Number	6		9	
Gestational age	27 (19–29)		30 (23–34)	
RPBC/FPV‡	0·39 (0·30–0·52)		0·38 (0·14–0·53)	
	Before	Δ	**Before**	Δ
pO_2 (*z* scores)	0·1 (−0·5 to 0·5)	0·01 (−0·03 to 0·04)	0·2 (−0·5 to 0·6)	0·31 (−0·20 to 0·64)
pCO_2 (*z* scores)	0·1 (−0·2 to 0·3)	0·20 (−0·10 to 0·30)	0·1 (−0·4 to 0·5)	0·01 (−0·01 to 0·01)
pH	7·40 (7·39–7·42)	0·02 (−0·08 to 0·10)	7·39 (7·36–7·42)	0·05 (−0·11 to 0·12)

Values shown are means (95% CI), except gestational ages, shown as medians (range). NS = not significant. Changes (Δ) in blood gases and pH = post transfusion minus pre transfusion values with 95% CI shown. ‡Ration of volume of red packed cells or platelets transfused to fetoplacental volume

Table: **Patient characteristics and cortisol and β-endorphin concentrations in fetuses undergoing fetal blood sampling and transfusion at the intrahepatic vein or the placental cord insertion**

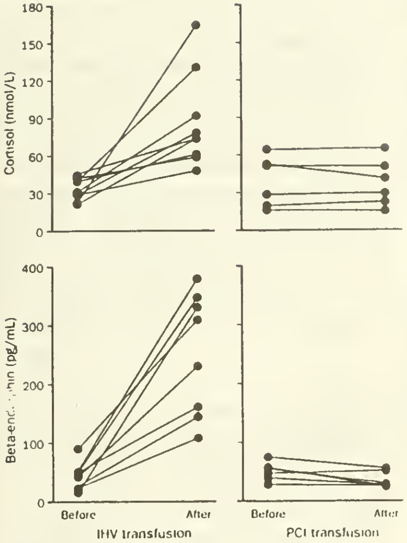

Figure 2: **Plasma cortisol and β-endorphin concentrations before and at the end of transfusion**

Both rose significantly in the intrahepatic vein (IHV) (p < 0·01 for both hormones), but not in the placental cord insertion (PCI) group

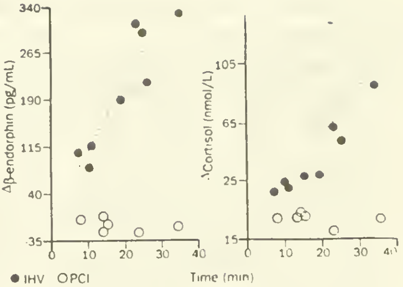

Figure 3: **Change in cortisol and β-endorphin concentrations with time at the two sites**

IHV = intrahepatic vein group (from first puncturing the fetal abdomen)
PCI = placental cord insertion group
IHV cortisol $r = 0·80$, $p < 0·05$, regression equation $(y) = 3·0(x)$.
IHV β endorphin, $r = 0·88$, $p < 0·005$, regression equation $(y) = 2·4(x)$
where y = post minus pre transfusion values and x = duration of needling

group comparisons. Associations with gestational age and stimulus duration were sought with standard linear and multiple regression.

The change in variables (post-transfusion minus pre-transfusion values) with time was compared between the sites of sampling by regression analysis between groups, power analysis showed that a sample size of 6 in each group (one tailed $\alpha = 0·05$, $\beta = 0·80$) was sufficient to detect a 40% rise in plasma cortisol and β-endorphin concentrations after transfusion based on pilot data and previous studies of fetal hormone measurements from uncomplicated fetal blood sampling at the placental cord insertion.[6,7] Since cortisol and β-endorphin may be released in parallel during stress, they are not independent, and hence the power of the study would be expected to be greater than indicated above. The effects of gestational age and the volume of packed red blood cells or platelets transfused (expressed as a ratio of the estimated fetoplacental volume[18]) on fetal hormone alterations were investigated by analysis of covariance. Correlations between cortisol and β-endorphin before and after transfusion were sought by Kendall rank correlation.

Results

Patient details and the cortisol and β-endorphin results for the group undergoing fetal blood sampling alone are shown in the table. Blood gases and baseline cortisol and β-endorphin plasma concentrations were not significantly different between the groups undergoing fetal blood sampling at the placental cord insertion and the intrahepatic vein. Blood gases were within the normal range for both groups. The median time to access the intrahepatic vein was 3·0 min (range, 1·5–10·0), and the placental cord insertion 0·7 min (0·5–2·5).

Transfusion (figure 2) resulted in a significant rise in fetal plasma concentrations of cortisol (48 nmol/L; 95% confidence interval [CI] 23 to 86, $p < 0·01$) and β-endorphin (207 pg/mL; [113 to 307], $p = 0·01$) in the intrahepatic vein, but not the placental cord insertion group (cortisol 1 nmol/L, [−6 to 2]; β-endorphin −12 pg/mL; [−27 to 3]).

Pre-transfusion hormone concentrations in the intrahepatic vein group were not significantly different from those in the placental cord insertion group ($p > 0·4$ for both hormones). In the transfusion group, blood gases (z-scores) and pH values were not significantly different between the two groups either before or after transfusion. Basal hormone concentrations were not significantly different between fetuses subjected to fetal blood sampling alone compared to those undergoing intravascular transfusion ($p > 0·6$ for both sites of sampling). Post-transfusion cortisol and β-endorphin were significantly correlated in the group transfused via the intrahepatic vein (Kendall's $\tau = 0·50$, 0·12 to 0·89, $p < 0·05$), whereas there was no correlation between pre-transfusion values.

There was no significant correlation between basal cortisol or β-endorphin concentrations and duration of fetal abdominal needling in the intrahepatic vein group. The rise during transfusion in both cortisol and β-endorphin in the intrahepatic vein group correlated with duration of needling (cortisol $r = 0·80$ [0·28 to 0·96], $p = 0·005$, slope = 3·0 [2·0 to 4·0], β-endorphin $r = 0·88$ [0·47 to 0·98], $p = 0·002$, slope = 10·6 [8·7 to 12·5]) and duration of transfusion (cortisol $r = 0·86$ [0·46 to 0·97], $p = 0·001$, slope = 2·4 [1·8 to 3·1], β-endorphin $r = 0·66$ [0·22 to 0·92], $p = 0·036$, slope = 8·1 [5·6 to 10·6]) (figure 3), but not time to access the vein (cortisol $r = 0·43$, β-endorphin $r = 0·13$, $p > 0·1$ for both). The ratio of the volume of the cell transfused to the estimated fetoplacental volume did n significantly influence these associations. Similarl baseline blood gases had no significant effect on the increa in either hormone. Neither hormone increased with time the placental cord insertion group.

Basal hormone concentrations did not corre significantly with gestational age. Multiple regres showed that gestational age did not significantly effect increase in cortisol and β-endorphin with duratio needling nor transfusion in the intrahepatic vein grou

Discussion

This study provides the first direct evidence that the fetus has a hormonal stress response to invasive stimuli. The rise in both β-endorphin and cortisol concentrations during transfusion (median increase 590% and 183%, respectively) was greater than that observed in preterm neonates undergoing surgery under light anaesthesia (approximately 80% and 105%, respectively).[2]

Uncomplicated fetal blood sampling at the intrahepatic vein was not associated with elevations in fetal plasma concentrations of β-endorphin and cortisol in the first 10 minutes, presumably because stress-induced elevations in corticosteroid and pituitary opioid peptide concentrations take longer than 10 minutes to become apparent in the plasma, as suggested by studies in animals[19,20] and preterm neonates.[21]

To obtain delayed samples we used the ethically acceptable model of therapeutic intravascular transfusion. Although the transfused fetuses cannot be considered normal by virtue of their anaemia, we took care to exclude other diseases and complicated procedures. Furthermore, there was no difference in basal hormone concentrations between alloimmunised and normal fetuses. The increase in plasma cortisol or β-endorphin concentrations in the group transfused via the intrahepatic vein was not due to any effect of the transfused blood or the transfusion procedure as these did not change with transfusion at the placental cord insertion. Similarly, increased transplacental transport of raised maternal cortisol is an unlikely explanation for the differential results with transfusion as this should be equally apparent with sampling at the placental cord insertion.

We found that basal fetal plasma cortisol and β-endorphin did not vary with gestational age; neither did the cortisol nor β-endorphin response to intravascular transfusion. Even the youngest fetus (23 weeks) in the group transfused via the intrahepatic vein showed a response (63% rise in cortisol, 492% in β-endorphin), which was not apparent in any of the fetuses transfused at the placental cord insertion. Previous studies of the effect of gestational age on fetal adrenocortical hormones have proved conflicting.[13,17,22] Our data suggest that such discrepancies might be due to the confounding effects of fetal stress, as in some studies umbilical blood samples were collected after labour.

It is not clear whether the rise of the stress hormones in the transfusion group was due to the initial piercing of the fetal abdomen or reflected continuing stress by the needle remaining in situ. The correlation with duration of transfusion and needling, but not time to access the vein, suggests that the rise in both hormones with transfusion more likely reflects the greater time interval from the initial puncture.

Anatomical studies show that cortical, subcortical, and peripheral centres necessary for pain perception differentiate and develop from early in the second trimester.[3] Cutaneous sensory receptors spread to the whole body of the human fetus by 20 weeks gestation, and the cutaneous flexor reflex response in infants of 28 weeks gestation is highly sensitive to painful stimuli.[23] Evidence from animal studies also suggest that fetal somatosensory afferents are activated in response to potentially painful stimuli.[24] Such nociceptor activation, for example, was first shown in vivo in fetal rats.[25]

We speculate that the rise in cortisol and β-endorphin this study is due to direct fetal hypothalamic-pituitar adrenal axis activation. The fetal pituitary is the main source of circulating β-endorphin,[15] and in animals the anterior pituitary accounts for most of the stress-induced secretion of β-endorphin.[20] Primate fetuses are known to mount a rapid adrenocortical response to intrauterine stress mediated via ACTH secreted by the fetal pituitary.[19] The fetal hypothalamic-pituitary-adrenal system seems functional from at least the beginning of the second trimester.[26] Extremely low-birthweight preterm infants show a normal pituitary response to corticotropin-releasing factor, and a normal adrenal response to ACTH stimulation.[21] Furthermore, suppression at the hypothalamic or pituitary level by prenatal treatment with corticosteroids leads to a decrease in fetal plasma cortisol concentration.[27]

Evidence suggests that the secretion of adrenocortical hormones in response to stress in the plasma of adults[28] and in the amniotic fluid of fetuses[29] is closely interrelated with endorphin release, as both this and ACTH are products of the same precursor molecule, pro-opiomelanocortin. Preliminary data in preterm neonates (Giannakoulopoulos et al; unpublished data) indicate that plasma β-endorphin shows a strong correlation with plasma cortisol. The correlation we observed in this study in post-transfusion (intrahepatic vein group) fetal plasma between the two hormones is consistent with their partial joint regulation by the fetal hyopthalamic-pituitary axis.

Since the mechanisms involved in pain perception are not fully understood, it is not possible to conclude that the fetus experiences pain; a hormonal response cannot be equated with the perception of pain. Our study shows that, as with neonates, the fetus mounts a similar hormonal response to that which would be mounted by older children and adults to stimuli which they would find painful. This is of relevance to the now commonplace intrauterine needling procedures on the fetus such as cyst aspiration, chest and bladder drainage, or tissue biopsy.[30] Further investigatio is needed into how these responses may be blunted b anaesthesia or analgesia.

Just as physicians now provide neonates with adequa analgesia,[5] our findings suggest that those dealing with t fetus should consider making similar modifications to th practice. This applies not just to diagnostic and therapeu procedures on the fetus, but possibly also to termination pregnancy, especially by surgical techniques involv dismemberment.

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Mr. CANADY. Thank you, Doctor.

Let me just say that I think that the testimony that we've heard makes very clear what the facts are here. It's unfortunate that those who have disseminated the information that is contrary to the facts that we've heard here were unable to be here or unable to present any medical testimony in support of the information that they have disseminated.

Now, Dr. Birnbach and Dr. Ellison, you head the two organizations that represent anesthesiologists and obstetric anesthesiologists and perinatologists. Did Kate Michelman of the National Abortion Rights Action League, Mary Campbell of Planned Parenthood, Dr. Lewis Koplick, or any official from the National Abortion Federation, consult either one of you about the accuracy of their claims that anesthesia administered to a mother kills her unborn child?

Dr. ELLISON. After I testified in the Senate in November, I did receive a call from someone from the National Abortion Federation who explained to me in detail the anesthetic technique and asked, "Would that change my opinion?" Frankly, I said, "Not only did it not change my opinion, it really gave me cause for concern about the health of the mother." They're giving doses of drugs that are capable—in fact, I'm surprised that they are not routinely producing a general anesthetic state in patients who—in mothers—without an anesthesiologist present. Admittedly, there has apparently been no maternal mortality from Dr. McMahon's experience, but they are giving very large doses of drug, much more than I would recommend.

Mr. CANADY. Dr. Birnbach.

Dr. BIRNBACH. When the article that you mentioned came out in the St. Louis Post-Dispatch, I called them to ask them how they had gotten such misinformation, and they said that—as to suggest that they might retract that, because I had already heard from people in St. Louis that people were reading this and were alarmed. And they told me that this was a fact that they had received from Mary Campbell. And I, then, after several days of trying, did get in touch with Mary Campbell. But her factsheet was already out at that point.

And I told her that there was no scientific basis for what she said on her factsheet. As a practicing anesthesiologist, I have administered larger doses than the doses that she claimed that Dr. McMahon was giving. The difference is that the patients that I administered the anesthesia to were asleep for 2 to 3 days and intubated on that dose, and the babies were fine. So that was my total contact with them.

Mr. CANADY. Well, are either of you aware of any action the individuals have taken to clear up the misinformation that they have disseminated?

Dr. ELLISON. I'm not.

Dr. BIRNBACH. No.

Mr. CANADY. Now at the risk of repeating some of the ground we've already covered, let me ask both of you, do you think that their is any anesthesiologist who would be able to defend the claim that anesthesia administered to a mother kills her unborn child?

Dr. ELLISON. Absolutely not.

Dr. BIRNBACH. There is no obstetric anesthesiologist who could even remotely come up with that because we administer anesthesia on a daily basis to women of all gestational ages without interfering with fetal development.

Mr. CANADY. Dr. Ellison, you have already touched on this, but let me ask Dr. Birnbach. In your professional opinion, would it be within accepted medical practice for a doctor who is not an anesthesiologist to administer the high doses of anesthesia that Dr. Koplick and Dr. Campbell claim Dr. McMahon administered?

Dr. BIRNBACH. Absolutely not. The doses that they are suggesting were given were 40 milligrams of midazolan, and that—which is an analgesic drug—is clearly enough to administer general anesthesia alone. But to that they added between 9,025 micrograms of fentanyl. That combination is probably enough to anesthetize five of my patients and keep them asleep for several hours. So, even if they were given incrementally over several hours, we are talking about massive doses of anesthetic that probably would put the mother's life at risk unless her respirations were taken care of by an anesthesiologist who was breathing for her.

Mr. CANADY. Dr. Chestnut, would you like to comment on that same question?

Dr. CHESTNUT. I agree with the statements made by both Dr. Ellison and Dr. Birnbach, and I am very skeptical that any physician would give those doses of drugs of Versed and fentanyl to any patient in an outpatient setting. And for any physician to do so safely would require the placement of an endotracheal tube, and would require the physician to support the ventilation and oxygenation of the patient for a prolonged period of time.

Mr. CANADY. Thank you.

Mrs. Schroeder.

Mrs. SCHROEDER. Thank you, Mr. Chairman.

First of all, I'd like to ask, do any of you here support *Roe* v. *Wade*?

[No response.]

Mrs. SCHROEDER. None of you? Does anybody support *Roe* v. *Wade*?

[No response.]

Mrs. SCHROEDER. No. OK.

Dr. ELLISON. Excuse me. I'm not sure what your question—are you saying the Supreme Court decision?

Mrs. SCHROEDER. Yes, the Supreme Court decision of *Roe* v. *Wade*.

Dr. ELLISON. I am not opposed to that.

Mrs. SCHROEDER. OK.

Dr. BIRNBACH. And I support that personally. However, the question that I was called here for today was——

Mrs. SCHROEDER. I understand that.

Dr. BIRNBACH. It was not what is my opinion about *Roe* v. *Wade*, but what is my opinion about anesthesia.

Mrs. SCHROEDER. Absolutely. Now the next question I have, do I take it by your appearing here that you support the bill? All of you would be supporters of this bill? I guess what I'm asking is—what I think I hear you saying is that there is no anesthesiologist or any practice that a recognized anesthesiologist could have that they could utilize in this type of procedure that would be humane. In other words, it almost sounds like you'll be moving a malpractice suit against any anesthesiologist that permitted or participated in a late-term abortion.

Dr. CHESTNUT. I think that's a misrepresentation of the testimony this morning. And I would also add to Dr. Birnbach's response that I have not read the bill and did not come here today prepared to comment on the bill one way or the other. But I stand by every word of the testimony that I have given regarding the effects of anesthesia on the mother and the fetus.

Mrs. SCHROEDER. No, I understand that, and I'm really not trying to be confrontational. I'm saying that if there were things that came out in this debate, that you think sent the wrong messages to women, I, too, would want to correct that. But I also want to make clear that you're not saying that there is no safe way, or there is no authorized way that a legitimate anesthesiologist could participate or deal with this type of procedure. You're not saying that. You're just saying that some of the things that you heard were wrong. Is that right?

Dr. ELLISON. Representative Schroeder, first of all, I'm here representing ASA, and I want to make it clear that they have taken no position on this or any other abortion procedure. We have members of our society that feel strongly on both sides, I'm sure.

In terms—what we're—what I believe all of us are concerned about is, we don't want pregnant women to defer necessary surgery out of fear that anesthesia is going to harm the fetus in any way.

Mrs. SCHROEDER. Absolutely.

Dr. ELLISON. And that is the extent of my testimony.

Mrs. SCHROEDER. And I believe you also testified that you do not believe that physicians should be sent to prison for having performed abortions.

Dr. ELLISON. That was in the question and answer section last——

Mrs. SCHROEDER. And that was your testimony, too?

Dr. ELLISON. That's right.

Mrs. SCHROEDER. And that was this procedure. Let me ask you as doctors, when a doctor has a very difficult decision to make, aren't they obligated to use the procedure that has the greatest reduction of risk to the woman?

Dr. CHESTNUT. I would believe so.

Mrs. SCHROEDER. And you, would you believe so?

Dr. BIRNBACH. I would agree with that statement.

Mrs. SCHROEDER. And would you agree with that, too?

Dr. WRIGHT. That's right, although some of the anesthetic techniques that we've heard described do not sound like they protect the health of the woman.

Mrs. SCHROEDER. I'm trying to get to where the bottom line is, because, as I said, what I had hoped the hearing would be about is what the President's letter was about, saying that *Roe* v. *Wade* talks about the health and safety of the woman, and I'm trying to find out if that's in conflict with the standard that the medical society would have. And it would seem to me that if your patient is the woman, and she comes in, and she's got a pregnancy that has gone terribly wrong or there is some critical health condition that has occurred—we have 100 percent agreement that the doctor should be focusing on his patient and what can be done to try and keep her health whole or keep her as healthy as possible. That would be the medical standard, right? So, the President's letter would be right on on that.

I also wanted to say that Dr. Campbell did testify fully in front of the Senate. I didn't put that in the record, but it is the full Senate record, and I think it is very, very important that if anybody has questions about that, they should look at that.

If this——

Mr. CANADY. The gentlelady's time has expired. We're going to have a second round.

Mrs. SCHROEDER. OK, thank you.

Mr. CANADY. Mr. Hyde.

Mr. HYDE. I thank you, Mr. Chairman.

Dr. Wright, I was fascinated by your—everybody's testimony, but your's in particular, because you talked about—you say that current data indicate that preterm neonates have greater pain sensitivity than term neonates or older age groups. You're talking about preborn babies, then, that they feel pain.

Dr. WRIGHT. They feel pain, and they feel it more than a term neonate does. And we know that because those 24-, 26-, 28-weekers that are delivered and are in the neonatal intensive care unit are now subjects of studies over the last few years that have confirmed that both they can feel, perceive pain, and their response is magnified.

Mr. HYDE. Now, Doctor, how—in your professional opinion—how early following conception can that fetus begin to feel pain?

Dr. WRIGHT. Begin to feel pain, the earliest reference I made was 7 weeks because of the sensation that's on——

Mr. HYDE. Seven weeks.

Dr. WRIGHT. Seven weeks.

Mr. HYDE. The mother hardly knows she's pregnant then.

Dr. WRIGHT. That's correct. And by 20 weeks——

Mr. HYDE. That little fetus is feeling pain?

Dr. WRIGHT. That's right.

Mr. HYDE. And you know, we have movements in this country to do away with leg clamps on animals because they feel pain. Cruelty to animals is condemned. We've had people go and sleep on icebergs to be close to baby harp seals, save the whales. Now you're telling us that Dr. Nathinson, who composed a film called, "The Silent Scream" referring to the feeling of pain by the unborn child, wasn't off the wall at all. They do feel pain?

Dr. WRIGHT. That's correct. And in response to that, just because we can't hear the cry doesn't mean that it's not there. And we can see it, as some of my colleagues have referenced by the fetoscopy procedure. We see it in the neonatal intensive unit. And, this procedure, if it was done on an animal in my institution, would not make it through the institutional review process. The animal would be more protected than this child is.

Mr. HYDE. Doctor, is there such a thing as a pain-free abortion for the fetus.

Dr. WRIGHT. No.

Mr. HYDE. Now we've talked about health. The gentlelady from Colorado has made much of the letter of the President talking about health of the mother. See, we talk about the mother. The absent element in this is the preborn child. We don't even think about that. I think the statistics are that over half of the aborted fetuses are girls. And "safe, legal, and rare"—there's nothing safe about an abortion. They're terminal.

But anyway—"health," the "health exception," now "health"—what people have to realize, has been defined by our all wise Supreme Court in *Doe* v. *Bolton*—"physical, emotional, psychological, familial, and the woman's age—relevant to the well-being of the patient." A state of well-being. So that's fine. That's "healthy." But if someone wants an abortion, and they're distressed that they can't have one, I guess their "health" is impaired, and that entitles them to one. And that's the great loophole in using health as defined by our Court as an exception to permit a partial-birth abortion. But, I'm sure the gentlelady understands that or will understand that, and I thank you.

Mr. CANADY. The gentleman from South Carolina.

Mr. INGLIS. Thank you, Mr. Chairman. I think this is a great day in the Congress. I've got a number of constituents who tell me all the time, and particularly my dad tells me, there should be a truth squad that descends on the floor of the House after outrageously false things have been said. And it should be the power of the Speaker, the person sitting in the Speaker's chair, to suspend proceedings until the truth squad can come on the floor and detail the inaccuracies of the things just said. So, it's a wonderful day, Mr. Chairman, for you to hold this hearing and to basically do just that, to have this truth squad descend and present this wonderful scientific evidence so that these folks who said all manner of irresponsible things are found out.

And I thought it was fascinating to hear the first question of the gentlelady from Colorado inquiring as to—trying to discern whether you would like to bend your science to fit some political ideology. And it was very interesting to see that this panel was very startled by the question and couldn't figure out whence cometh Mrs. Schroeder. They wanted to know what's relevant about that. There was a quizzical look on every one of the four faces out here that, "What are you talking about? We're talking about science."

It's a wonderful day when we have scientists, people who care for women in need, care for unborn babies, come here with scientific evidence to correct the absolutely irresponsible statements by some people that are motivated by an absolutely blinding conviction that a woman should be able to exterminate her unborn child. They are so blinded by it, that conviction, that determination to make the law of the land and to preserve that as the law of the land, that they are willing to pervert any manner of science, and to say anything at any day, even on the floor of the House of Representatives.

So, Mr. Chairman, I am just enjoying the testimony of these folks and think that it is a fascinating day to have the truth squad descend.

Mr. HYDE. Would my friend yield to me?

Mr. INGLIS. I'd be happy to.

Mr. HYDE. I've just come across an astounding letter that was handed to me by counsel. I guess it's over on the table. It's from a Dr. Mitchell Creinin, assistant professor, director of family planning and family planning research at McGee Women's Hospital in Pittsburgh. And I quote—and I'm going to ask each of you if you can validate this statement—"I am the director of family planning and family planning research in the department of obstetrics gynecology and reproductive sciences at the University of Pittsburgh. As a physician, I can assure you there is no such thing as pain to a fetus. Plain and simple, pain does not exist to a fetus. Any doctor who states otherwise is flat out lying and twisting medical data."

Dr. Ellison, would you agree with that?

Dr. ELLISON. I read that letter over there, and I find it inconceivable that any physician would make a—would attach his name to a letter like that.

Mr. HYDE. Dr. Birnbach.

Dr. BIRNBACH. Having administered anesthesia for fetal surgery, I know that on occasion we need to administer anesthesia directly to the fetus because even at these early ages the fetus moves away from the pain of the stimulation. So I cannot agree at all.

Mr. HYDE. Dr. Chestnut.

Dr. CHESTNUT. I agree with my colleagues and would also note that at the University of California at San Francisco, which is the leading center in the world for performance of fetal surgery, that even though the mother is receiving heavy, deep doses of general anesthesia, those physicians give additional anesthetic drugs directly to the fetus during surgery in order to make certain that the fetus does not experience pain during the procedure.

Mr. HYDE. Thank you.

Dr. Wright.

Dr. WRIGHT. There is no science to substantiate that letter. I believe all of us submitted to you journal articles that have been reviewed by our peers—and I make particular reference to a landmark article in 1987 in The New England Journal, and their phrase was, "there is no doubt about cortical function and the perception of pain in children of this age." There's no science behind that.

Mr. HYDE. I ask—and thank you all—I ask unanimous consent that this letter from this Dr. Creinin be placed in the record.

Mr. CANADY. Without objection.

Mr. HYDE. Thank you.

[The information follows:]

MAGEE-WOMENS HOSPITAL

March 20, 1996

Representative Charles Canady
US House of Representatives
Washington, D.C.

Dear Representative Canady:

I am writing to you because I am very concerned about potential legislation against the intact Dilatation and Extraction (D&X) procedure. Most pertinent to me now is the farce of concern about fetal pain.

I am the Director of Family Planning and Family Planning Research in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Pittsburgh. As a physician, I can assure you that there is no such thing as pain to a fetus; plain and simple, pain does not exist to a fetus. Any doctor who states otherwise is flat out lying and twisting medical data.

Pain is something that is only experienced at a conscious level. For example, a person undergoing surgery under general anesthesia does not feel pain when the incision is made in her abdomen because she has no consciousness. When she is awakened from the general anesthesia after the surgery is completed she then experiences pain because she is again conscious. Similarly, a fetus in the uterus has no level of consciousness; therefore, no pain can be experienced.

A second point of clarification in regard to pain has to do with ways in which researchers attempt to measure or identify "pain" in an *in utero* fetus. These research studies often attempt to measure pain by introducing a stimulus that the researcher perceives will be painful then measures reflex responses to indicate that the fetus "feels pain." Unfortunately, this "leap of faith" cannot hold true based on basic developmental principles. First, reflexes are established early in embryonic development and these reflexes are autonomic meaning that they are set up as reflex arcs through the spinal cord and do not involve the brain. Thus, if a researcher attempts to measure, for example, fetal movement or heart rate as a measure of pain this is an inaccurate measure. A fetus responds with these autonomic reflexes to stimuli, not to "pain." If a fetus moves, for example, its heart rate increases; this is not because it feels pain but because it is an autonomic reflex. Again, this also has nothing to do with brain function or perception of pain. An example that you could understand would involve a person in a coma. If the doctor used a reflex hammer on his knee, the patient would still kick his lower leg up in the air. This person in the coma does not do this because he feels pain nor because his brain perceives that something is painful and makes the leg kick. The lower leg moves because of an autonomic reflex arc that exists from the knee to the spinal cord and back to the knee. It is automatic and does not involve the brain.

Obviously, these examples show even more conclusively that lawmakers are not properly trained to make medical decisions an often not fully able to understand medical data. As such, lawmakers should not even be attempting to make decisions about "fetal pain." The only appropriate legal decision would be in favor of the right and responsibility of the physician to provide appropriate surgical care when indicated. The decision of how a procedure is to be performed (i.e., how an abortion is to be performed), as long as the method is safe and effective, should be between the doctor and patient.

Thank you for your time and consideration.

Sincerely,

Mitchell Creinin, M.D.
Assistant Professor
Director of Family Planning and
Family Planning Research

Mr. CANADY. We are going to have a second round of questions now.

In the course of your testimony, reference was made to a written statement that was submitted to the subcommittee by Dr. McMahon. And I want to read from that statement. This was submitted on June 23, 1995, and it's on page 5 of the letter that was submitted by Dr. McMahon. The paragraph I am going to read is somewhat ironically, in my view, under a bold heading, "Misconceptions." It says, "The fetus feels no pain through the entire series of procedures. This is because the mother is given narcotic analgesia at a dose based upon her weight. The narcotic is passed, via the placenta, directly into the fetal bloodstream. Due to the enormous weight difference, a medical coma is induced in the fetus. There is a neurological fetal demise. There is never a live birth."

Would any of the witnesses like to make any additional comments on that statement and the various elements in that statement?

Dr. ELLISON. I would comment that that seems to be the origin of the misconception that we're here to refute. I believe that Dr. McMahon's statement about their giving a dose 40 times what the fetus—but they're not giving it to the fetus. They are giving it to the mother. And only a very small fraction of that crosses that placenta barrier and is transmitted to the fetus.

Mr. CANADY. Doctor, do you have any idea what may have led Dr. McMahon to make this statement, what may have led to a misunderstanding that could have caused it?

Dr. ELLISON. A gross misconception on his part. I can't conceive of why he would say that.

Mr. CANADY. Dr. Birnbach.

Dr. BIRNBACH. I would have to agree. The mother is given a narcotic analgesia dose based on her weight. That's true, and I do that in practice every day—in cesarean section under general anesthesia, the baby is wide awake, despite the fact that we gave enormous doses of anesthesia to the mother. The anesthetic dose not all cross the placenta, and that that does gets metabolized by the liver. Quite often the baby can be somewhat sleepy or wide awake. But there is no question of fetal demise.

Mr. CANADY. Let me yield to the gentlelady from Colorado. Mrs. Schroeder, do you believe that the statement that was contained in Dr. McMahon's testimony that we've been discussing was inaccurate?

Mrs. SCHROEDER. I want to say that I'm not a doctor, and I feel very uncomfortable—Congress sitting here deciding what dosage, and how you give it, and what was stated, and which doctor was——

Mr. CANADY. Of course, that's not, that's not really the question.

Mrs. SCHROEDER. But we're not trying doctors today. We're talking about a bill that's going to limit the choices doctors have. And I'm trying to say, we can always find things that we can pick away that somebody has said who was a witness for one side or the other, but the bottom line is: Why do we feel free to try doctors here? I mean——

Mr. CANADY. We're not trying any doctors. We're trying to get some facts out here that are important to the health of women.

And you've heard the testimony from the doctors here today who believe that this myth about the impact of anesthesia on children in the womb is something that may cause women who need to have a surgical procedure to avoid having the treatment that they need because of the fear that they feel for the impact on their fetus. What we're trying to do is clear the air on that.

I understand that, regardless of what the facts are on this particular question, you will still oppose the bill, and that's the choice that you make. And I understand that their are other grounds on which that position can be taken, but I think that it is very important for us in the Congress, for us to clear up this misconception which is posing a threat to the health of women. And again, I can't—you have to speak for yourself.

Mrs. SCHROEDER. Well, if the gentleman will yield, I now feel like the gentleman has decided to try me. If the question is about pain and how much dosage you issue of anesthesiology, and so forth—I come from a family filled with anesthesiologists, and the last thing I'm going to do is sit up here and get involved in this because I know how tough to call it is. And I have great respect that they are not going to do something that is harmful. If the issue is about pain, I can tell you, as someone who's been through it, birth is painful. Birth is painful to the child. Fetal surgery is painful. Other forms are painful. If we're trying to find a pain——

Mr. CANADY. My time has expired. The gentlelady from Colorado is recognized.

Mrs. SCHROEDER. I thank the gentleman. I can't quite figure out where we're going with all of this. I think the bottom line—well, let me ask this question: Is there anything in anyone's training that would lead you to believe that one method of an abortion is less painful than another when it comes to late-term? So is it proper for this bill to ban one form of late-term abortion because this is more painful than any other term of late-term abortion procedure that is being used? You understand?

I mean, what you're testifying on is a bill that says that one form of late-term abortion is hereby criminal to perform. Is this one form so bad compared to any form of late-term abortion or so much more painful compared to any other late term abortion that the Congress should step in and act? I mean, that's what we're talking about here.

Dr. ELLISON. I have to pass on that in that I don't know what other types of late-term abortion there are. I think you're asking a group of anesthesiologists, and with the possible exception that Dr. Chestnut might know since he's trained in obstetrics also, we don't do this procedure. So I've never actually seen it done.

Mrs. SCHROEDER. I think it's done very rarely because, fortunately, very few people have to resort to it, thank goodness. But the question is, are there other forms that we don't know about? Now that we're going to become medical doctors, should we have Ob/Gyn's in here to tell us what the different forms are and why this one should be outlawed over any other? My next question is, do Ob/Gyn's make these choices lightly?

Dr. ELLISON. I can't believe they would do that. They'd give the same careful consideration to the health of the mother that we do when we consider the anesthetic.

Mrs. SCHROEDER. I would certainly think so, too. And that's why I guess I'm so troubled by this.

In looking at the health of the mother, preserving her future reproductive capacity could also be a valid factor, wouldn't you think? Doesn't she have the right to continue to try for successful mother had, or do you only get one shot at this?

Dr. ELLISON. Yes.

Mrs. SCHROEDER. You would agree with—that a doctor could reasonably take that into account and not think she was just being selfish?

Dr. ELLISON. Yes.

Mrs. SCHROEDER. Let me ask about pain, then. We've heard a lot about pain here, but I assume that when there's fetal surgery there's pain. Is that correct?

Dr. BIRNBACH. Yes, there is evidence that there is pain.

Mrs. SCHROEDER. And so what you do in that case is you directly administer the anesthesia to the fetus, right?

Dr. BIRNBACH. Either you administer more anesthetic to the mother or you administer anesthetic directly to the fetus, correct.

Mrs. SCHROEDER. And, of course, with birth there's pain.

Dr. BIRNBACH. Not if the patient has an analgesia onboard, like an epidural.

Mrs. SCHROEDER. You mean for the patient. But there can be pain for both the mother and the child. Birth is—I mean, as I remember it——

Dr. BIRNBACH. Personally, I don't remember my birth. [Laughter.]

Mrs. SCHROEDER. I remember giving birth. I'm like you, I can't remember birth itself, but it is not exactly a pain-free experience. So, if the idea is we should ban anything that has pain, Congress should ban any procedure that has pain, then aren't we stepping into a real muddy field?

Mr. HYDE. My dentist would hate to hear you say that.

Mrs. SCHROEDER. That's right. I'd never go to one again.

Does anesthesia administered to the woman provide any pain relief to the fetus? Is that what you're saying, it does not?

Dr. CHESTNUT. What we have said—I think this is consistent with the other testimony this morning—is that, yes, these drugs do cross the placenta, and, in the case of large doses, may or may not provide partial pain relief. But the ability of any physician to predict the amount of pain relief provided to the fetus, that just doesn't exist in clinical practice. And, as Dr. Birnbach and I have both said, for that reason, at fetal surgery, surgeons give additional doses of drugs directly to the fetus, despite the fact that the mother is already receiving general anesthesia, and I might add, a deep level of general anesthesia.

Mrs. SCHROEDER. I see my time has again expired, Mr. Chairman. Thank you.

Mr. CANADY. Mr. Hyde.

Mr. HYDE. Dr. Wright, it seems we're getting into pain, but anesthesiology and pain are certainly linked, I guess. I'm trying to think of the methods of abortion, and we're going to ask you about pain. Dilatation and curettage, that's where they reach in with an instrument, a sharp instrument, and dismember the fetus and ex-tract the fetus. Would you think, in your professional opinion, that fetus feels some pain in undergoing the process of dilatation and curettage?

Dr. WRIGHT. While the mother is only under local anesthesia?

Mr. HYDE. Yes.

Dr. WRIGHT. Yes.

Mr. HYDE. All right, then there's the salting-out method. That's where they inject a saline solution into the womb, and that literally scalds the unborn child, and finally the child is expelled. Or the fetus, to be as impersonal as we can, is expelled. Would you say that that fetus would feel pain while undergoing the salting-out process?

Dr. WRIGHT. I would believe so. I'm not an abortionist nor do I practice obstetrics anesthesia. But, based on the scientific evidence I gave you earlier about more pain fibers on the skin than on full term or on older children, yes.

Mr. HYDE. I should think scalding the unborn child in the womb would be painful.

Then there's the suction machine. They attach a machine, and it literally pulls the child to pieces out of there. One could assume that's a painful process for the unborn. Now we're going to focus—leave the autonomous woman for a second and focus on the child.

Then we have the partial-birth abortion where the child is almost totally extracted from the birth canal and the scissors goes in the back in the neck, and then they suck out the brains.

So we're talking about a lot of pain, I would think, based on your testimony and based on what I heard from the other gentlemen who are superior anesthesiologists. So I think it's an accomplishment if we could ever get a concession that the unborn child feels a hell of a lot of pain in this process, and maybe we ought to consider that in weighing the advisability of abortion as an answer to lots of problems.

I thank you, Mr. Chairman.

Mr. CANADY. The gentleman from South Carolina.

Mr. INGLIS. Thank you, Mr. Chairman.

Following up on Mr. Hyde's line of questioning there, I thought that it was very interesting that Mrs. Schroeder was making a list of things that create pain, and she never mentioned abortion. She mentioned fetal surgery. She mentioned birth. But she never mentioned abortion.

Mrs. SCHROEDER. Would the gentleman yield?

Mr. INGLIS. I would be happy to. Let me yield to you and ask you this question. Do you think that a child—a fetus, since you want to call it that—feels pain during the abortion techniques that Mr. Hyde just enumerated?

Mrs. SCHROEDER. The question I had had for the panel was——

Mr. INGLIS. No, no, no. I'd be happy to yield to you only for that purpose.

Mrs. SCHROEDER. No, but you were coloring my question—and I do believe I asked the panel, were they aware that other procedures were less painful, and they said, "No." So, you're——

Mr. INGLIS. Are you going to answer now?

Mrs. SCHROEDER. I do not know. I am not——

Mr. INGLIS. Oh, now wait a minute, wait a minute. You said a minute ago that surgery creates pain. You know that. You said you know that.

Mrs. SCHROEDER. I would also say——

Mr. INGLIS. Somehow you know that. I don't know how, but——

Mrs. SCHROEDER. That for the mother creates pain——

Mr. INGLIS. No, no, no, we're not talking about that, madam.

Mrs. SCHROEDER. I would say a loss of health——

Mr. INGLIS. I'm asking you a question about——

Mrs. SCHROEDER. What is this?

Mr. INGLIS. I would be happy to yield to the gentlelady to answer this question: do you think that in an abortion—following this line of questioning because it relates to your earlier omission of a major procedure called abortion, as to whether that creates pain for the child, would you answer that?

Mrs. SCHROEDER. I am saying there is pain in birth, there is pain in probably everything that's out there, and there is pain in the death of the mother—

Mr. INGLIS. And there's pain in abortion? Is there pain in abortion?

Mrs. SCHROEDER. Well, I'm sure there is pain in abortion for both the mother and I assume——

Mr. INGLIS. And, wait a minute, wait a minute. And the what? And the what?

Mrs. SCHROEDER. I am not—I have not seen medical studies that are out——

Mr. INGLIS. Wait a minute. You just stopped short. You were about to say "and the baby." But your ideology stopped you, didn't it? It gripped you there. You couldn't go forward with that line of reasoning.

Mrs. SCHROEDER. Look, I once again feel like this is a witch trial, and I——

Mr. INGLIS. No, no, no, I'm just asking you because I think it's a major concession by you and all these folks assembled with you.

Mrs. SCHROEDER. No, I'm trying to say, and I have said from day one, this is a difficult medical choice between the mother's health and the fetus and the potential child, or whatever. And there's a whole lot of things that go into this. It's a very difficult choice of any person, be they medically trained or nonmedically trained.

Mr. INGLIS. No, we're getting back into this whole put your head in the sand, forget all the science, just sort of go back to your ideology. I've asked you a simple question. You just heard some very interesting testimony here about pain, and you stopped short of saying that abortion causes pain for the child.

Mrs. SCHROEDER. No.

Mr. INGLIS. For the fetus, as you want to call them, impersonally.

Mrs. SCHROEDER. No, I didn't say that. I said that I would stipulate that there is pain involved in everything. I do not know——

Mr. INGLIS. Including an abortion? Wait a minute. Would you stipulate that it includes pain in an abortion for the child?

Mrs. SCHROEDER. I believe—do you want me to have the record read back? I do believe that I said to the witnesses, "Is this procedure that we are trying to outlaw and make criminal more painful than any other abortion procedure?" And they didn't know, and I said, "I don't know." And I don't think anybody——

Mr. INGLIS. I think it's just fascinating that you continue to stop short of admitting that abortion is painful to the fetus.

Mrs. SCHROEDER. No, that's not what I said.

Mr. INGLIS. You said that surgery on the fetus is painful. You said that birthing the fetus is painful.

Mrs. SCHROEDER. Is the gentleman saying that we should ban things on how painful they are? So the most painful things——

Mr. INGLIS. No, I'm just seeking a major concession—if the gentlelady will suspend. I'm just seeking a major concession from your side, and that is that a child in utero is a—capable of feeling pain. It is therefore something that we attach to humanity. And then you could go on that.

Mrs. SCHROEDER. Do you think that the mother feels pain?

Mr. INGLIS. Absolutely.

Mrs. SCHROEDER. Do you think the family feels pain? Do you think the death of a mother could be painful?

Mr. INGLIS. Now we're getting to—you're lapsing into your ideology.

Mrs. SCHROEDER. Oh, oh, oh, we don't want to go that way. No, no, no, no, no. Look—I'm saying that the pain——

Mr. HYDE. Will the gentleman yield?

Mr. INGLIS. I'd be happy to yield to the gentleman from Illinois.

Mr. HYDE. There's lots of pain in this life.

Mrs. SCHROEDER. There's lots of pain in this life.

Mr. HYDE. If the gentlelady—there's lots of pain in this life. Our job as human beings ought to be to minimize the pain.

Mrs. SCHROEDER. Absolutely. Well, that's right.

Mr. HYDE. Especially gratuitous pain.

Mrs. SCHROEDER. Well, exactly. And what we're trying to do is say these are difficult choices that everybody is trying to weigh. And that's what it's all about. If we don't want to make criminal anything that's painful because you could be making criminal things that are painful——

Mr. CANADY. The gentleman's time has expired.

Mr. INGLIS. Thank you, Mr. Chairman.

Mr. CANADY. The gentleman from Virginia.

Mr. GOODLATTE. I'd like to follow up on that same line of questioning but with the panel, and ask them to comment on the statements by another individual, Dr. Martin Haskell, who performs partial-birth abortions in Ohio and was asked in a Cincinnati medicine article whether the unborn child feels pain. He answered by saying, "Neurological pain and perception of pain are not the same. Abortion stimulates fibers, but the perception of pain, the memory of pain that we fear and dread, are not there. I'm not an expert, but my understanding is that fetal development is insufficient for consciousness. It's a lot like pets; we like to think they think like we do. We ascribe human-like feelings to them, but they are not capable of the same self-awareness we are. It's the same with fetuses. It's natural to project what we feel for babies to a 24-week-old fetus."

That's Dr. Haskell's statement. I would like to ask the panelists to give their opinion on that, perhaps starting with Dr. Wright.

Dr. WRIGHT. Well, I don't know of any scientific evidence that would back up his opinion, and that's what I would call it, his opinion. Pain is a multidimensional phenomenon. It has everything from reception of the pain, transmission of it. It's incorporated into your memory. In fact, pain, many experts say, by definition is important when it becomes remembered, or when we have memory of it. And we do know that these preterm infants have memory, and that they show it after delivery. We also know from studies in neonatal intensive care units that they have procedural memory. Because they cannot vocalize it or verbalize it in a way that says to us, "I have pain," like an adult patient can by pushing a button for a nurse in a hospital bed, we disregard that many times. We know from the studies that I mentioned earlier, the EEG studies, the potential studies, their wakefulness, their sleepfulness, those all reflect a human that is capable of perceiving and responding to pain.

You know, I was thinking about this as you were reading that quote. Those of us who practice anesthesia, we frequently have signs up in our operating room, "Be careful what you say. Patients may be listening." The patient is anesthetized, but we know that people can bring in, perceive, integrate, and remember things even when under anesthesia.

Mr. GOODLATTE. Thank you.

Anyone else care to comment on that quote? Dr. Chestnut.

Dr. CHESTNUT. I think that many of us have observed the responses of infants born at 24 weeks' gestation in a neonatal intensive care unit, and the responses that they exhibit in response to procedures suggests that at that age they do experience pain.

Mr. GOODLATTE. Thank you.

In a National Abortion Rights Action League press conference, Kate Michelman, the group's president, said, "The fetus undergoes demise before the procedure begins, and because of the anesthesia, which is, you know, something like 50 to 100 times what a fetus can withstand because it's given according to the weight of the woman." That's her quote.

Then during a radio interview, Ms. Michelman said, "The other thing that I want to say is that they have, the other side, grossly distorted the procedure. The anesthesia that they give the woman already causes the demise of the fetus. That is that it is not true that they are born partially. That is a gross distortion. And it's really a disservice to the public to say this."

I ask the panelists, aren't Ms. Michelman's statements a distortion themselves, and isn't that a disservice to the public, to create that perception on the part of pregnant women and their children that they—isn't she promulgating a myth about anesthesia killing the unborn child?

Dr. ELLISON. I would agree. I think that this entire myth originating with McMahon, and being promulgated by, I guess, his adherents, is most unfortunate.

Dr. BIRNBACH. That's why we're here today. This myth is being promulgated, and it's being picked up in the lay press. And our patients are reading that, and there is no truth to that.

Mr. GOODLATTE. Thank you. Anyone else care to——

Dr. CHESTNUT. A gross distortion of reality and clinical medicine, and I wish I could ask you, if I were permitted to ask a question, and I know that I'm not, how often does this type of gross misinformation get presented to the Congress?

Mr. CANADY. Too often, too often.

Mr. GOODLATTE. Thank you, Mr. Chairman.

Mr. CANADY. We're going to go through, I think, just one more round of questions.

I'd like to follow up on the comments about the reports in the press, and I'd like to ask particularly Dr. Ellison and Dr. Birnbach what your appraisal is of the way the press has handled the information related to anesthesia and partial-birth abortion.

Dr. ELLISON. I would say that if you would read in the press, for example, what was said last November, you would wonder if I was in that hearing room. The quote that Dr. Birnbach made in the Marie Claire magazine, I was at the same table as Dr. Campbell when that statement was made, and no mention was made of the fact that I publicly disputed her claims. And——

Mr. CANADY. Or that you're the president of the American Society of Anesthesiologists?

Dr. ELLISON. Right.

Mr. CANADY. Dr. Birnbach.

Dr. BIRNBACH. If I were to put it in one word, it would be "irresponsible." And I have spoken to most of the people who've written those newspaper and magazine articles, and they are trying to push one side of this, and have latched onto the fact that maybe anesthesia does cause some problem because some doctors said so to Senate. The fact that that doctor was not an anesthesiologist and had no knowledge about anesthesiology, they don't particularly care about.

So, I would think that the fact that at this point Dr. Ellison has testified, I have yet to see any major newspaper say, "Hey, it's OK out there. You can get an anesthetic if you need it. If you want analgesia for labor, since labor is painful, go ahead, it's safe for the baby." But plenty of magazines and newspapers still are latching on to this fetal demise theory.

Mr. CANADY. OK, thank you very much.

I have a question for Dr. Chestnut. Doctor, you are both an anesthesiologist and an obstetrician, as we have noted already today. Nurse Brenda Shafer, who will be testifying on a later panel today, previously testified before the Senate Judiciary Committee that she witnessed Dr. Haskell perform a partial-birth abortion, and before he inserted scissors into the back of the baby's skull, and I quote, "The baby's little fingers were clasping and unclasping, and his little feet were kicking." Is this description consistent with a baby being delivered from the womb after the application of local anesthetic?

Dr. CHESTNUT. Yes, it is. What she has described is what I observed several times during vaginal breech deliveries, more often later in gestation. And in babies who might be delivered with the mother having received local or epidural anesthesia, that description would be consistent.

Mr. CANADY. Thank you. Dr. Chestnut, let me also ask you about this: Dr. Martin Haskell wrote a detailed description which he delivered at a medical conference of how to perform what he called a "dilation and extraction" abortion. He advocates the technique as a "quick, surgical outpatient method that can be performed on a scheduled basis under local anesthesia." In his description he states, "The surgical assistant administers 10 IU Pitocin intramuscularly. The cervix is scrubbed, anesthetized, and grasped with a tenaculum. Lidocaine 1 percent with epinephrine, administered intracervically, is the standard anesthesia."

What effect would this anesthesia have on the unborn child?

Dr. CHESTNUT. The anesthetic drug itself would be expected to have no effect on the infant. Occasionally during performance of a similar procedure called "paracervical block," the local anesthetic might interfere with blood flow to the placenta and oxygenation of the baby which could cause the baby's heart rate to drop. That would be in the minority of cases, and, even in those cases, the infant would be expected to recover.

Mr. CANADY. Thank you very much.

Mrs. Schroeder?

Mrs. SCHROEDER. Well, Mr. Chairman, I'm almost as confused not as I was when this hearing began as to what this hearing is about. This bill went through here with rapid-fire delivery, and the chairman at that time didn't even want to let me ask questions. I remember we had a bell go off for a vote. We dropped one panel. It was over. The bill was out of here. It was on the floor. We're now told we're going to accept the Senate version without going to conference. This is going to be the law of the land, and here we go.

I guess we're trying somebody here. I can't tell whether we're trying other doctors, whether we're trying the press for misinformation in their stories, whether we're trying advocates of one side or the other. It seems like we're trying somebody here, and they're not here to answer, and that doesn't make sense. I think the bottom line——

Mr. CANADY. If the gentlelady will yield——

Mrs. SCHROEDER. No, let me use my time please.

I think who we are really trying here is American women, and that's why I brought these pictures of American women who have had their pregnancies go seriously wrong late term; they have gone to medical doctors, and in some cases medical doctors have said that one procedure was safer for them specifically rather than another, depending on their health, depending on their condition, and so forth.

And so I think this is kind of a new American witchcraft trial, that any woman who will go to their doctor, and any doctor who would deal with this woman's condition, then, is a criminal. And I do not think that that should be the law of the land. That is not the law of the land.

Mr. CANADY. Will the gentlewoman yield?

Mrs. SCHROEDER. But I understand that the gentleman would like that to be the law of the land.

Mr. CANADY. But let me make the point, none of these witnesses have said that. And let me also say——

Mrs. SCHROEDER. Let me continue my time, Mr. Chairman. Because these witnesses have said that they are here advocating that this specific procedure be made criminal. These gentlemen and these witnesses have not said that this specific procedure is more painful than any other procedure that is still going to be lawful I don't think they are advocating that the Congress outlaw procedures that are painful. I think that what they are saying, some information got out that they thought might be harmful to the general group of women; that, when they came in to deliver babies, it might affect their decision as to whether or not to have anesthesia, and that they want to make sure that women have the right information about that. And that's fine, and I'm delighted to have that. But that has absolutely nothing to do with whether or not this Congress should outlaw a specific procedure that has been legal up to now just because some misinformation got out twirling around the debate on this issue.

And so that's why I just find this so amazing, when at the very same time we're going to take up the assault weapon ban tomorrow, and we're going to lift it, and we're not going to have a hearing on it. I think that there's pain felt by anyone hit by an assault weapon, but, nevertheless, that pain doesn't matter. We're going to lift that ban, and we're going to arm America's kids once again. Go for it. Now, if pain is our thing, then we ought to have that ban. Let's talk about the pain in the emergency ward felt by people who are victims of assault weapons.

And so I just am very confused. I see this as just a real distraction, and I really am very saddened that this is all going on because I think that these are private, difficult, painful decisions. These women, whose pictures they have willingly let us put up there, have gone through this. This is not something that you want to air in public. I have been there. I have sat there and looked at a doctor in the eye and had to make these kind of decisions. And I damned well wouldn't want to know that a bunch of Congressmen had came in and said, "Oh, no, no, that may be the best for you, but we don't want you to have that procedure. We want something that is much higher risk to you."

I don't think people feel the Congress has that right and their government has that right. I think we still trust medical doctors enough to feel that they are going to make the right decision in that point based upon what everybody wants and the information. And based on these answer——

Mr. CANADY. The gentlelady's time has expired.

Mr. Hyde.

Mr. HYDE. I thank the chairman.

This is not a pleasant debate, but it is one we dare not avoid. The gentlelady is affronted that Congress people, especially the male of the species, would dare intervene in a decision by a woman to exterminate her unborn child. And that's a tough hurdle to get over. I simply suggest to the gentlelady that the defense of a defenseless, vulnerable, preborn child, when the mother, who should be its, his or her, natural protector, becomes its deadly adversary, is the business of everybody.

Mrs. SCHROEDER. Would the gentleman yield?

Mr. HYDE. And that killing an unborn—killing an innocent life is never a private matter. John Donne told us that, "Every man's death diminishes me for I am involved in mankind."

Mrs. SCHROEDER. Would the gentleman——

Mr. HYDE. In a moment.

Choice, a woman's choice—we're all for choice. But can you choose just anything? There's only one choice, a dead baby or a live baby. And once the baby is there, you have to deal with that, not just sweep it under the rug. And it seems to me that the protection of innocent human life is a noble thing. And I regret that it's intrusive. I regret that under the "me over thee" philosophy, the total autonomy of one person, even to the extent of exterminating a human life once it's begun, is something that I personally reject. And I think that people have a duty to save innocent human life. And it's painful, and it's hard, and it's difficult, and it's tough love, and our duty goes well beyond just helping to save that life. It's protecting and nurturing that life, and I know that. But, I just—what's painful to me is that the gentlelady defends this process. Is nothing beyond the pale? When is that little child going to get the constitutional right of equal protection of the law? Is it a matter of 2.5 inches? To get that head out of the canal, then is she entitled to be protected? Not only that child, but the progeny of that child, generations are eliminated, wiped out all to fulfill a need, perhaps of the woman, and God bless her, and God help her.

But this is not a pleasant responsibility, but the protection of innocent human life is what doctor's do, and it is what we ought to do as human beings. And we ought to be helpful to a woman who has that very painful decision. We're not trying to outlaw things that are painful. We're trying to narrow the incidence of gratuitous pain. And human life raises many problems. And we've all encountered them.

And I yield to the gentlelady.

Mrs. SCHROEDER. I thank my chairman, and I truly respect the depth of his feelings on this. I'm sure he would not want to brand these families, though, as selfish, who made a decision to save the life of the mother or to protect her from——

Mr. HYDE. I'm always for the life of the mother; the gentlelady knows that.

Mrs. SCHROEDER. That's right.

Mr. HYDE. The claim for life is equal.

Mrs. SCHROEDER. Or protect her future ability to have children. And I guess, Mr. Chairman, why I'm so puzzled by this, as one whose gone through this, what you want is, you want a child so badly that, if you outlaw safe, late-term abortions, maybe some people will then be forced to make a decision much earlier about their health and life that I don't think that they should be forced to make by the Government. Now, you know, that's their own personal choice, and they should be allowed to do that. But if we start outlawing certain procedures at that late level, and you know you are a high-risk pregnancy——

Mr. HYDE. My time is rapidly diminishing——

Mrs. SCHROEDER. So that's what I am concerned about.

Mr. HYDE. So let me just say that I think Government has one primary function beyond distributing the mail and defending and collecting taxes: protecting the weak from the strong. And that's what we do when we resist abortion.

Mr. CANADY. The gentleman from South Carolina.

Mr. INGLIS. Thank you, Mr. Chairman.

Briefly, I just thank again this panel for helping us. Dr. Chestnut, the answer to your question is, too often in this House we have a problem with people disseminating completely erroneous information. And it sure is wonderful to have four scientists, practicing physicians, come and clear up some real misconceptions and some absolutely, grossly inaccurate statements by people who are motivated by a blinding agenda that causes them to subjugate every fact to that agenda. And so it's wonderful. I appreciate the time you've given us.

And, Mr. Chairman, I'd also just say, briefly, that I feel for the gentlelady from Colorado because she is here in a position of having to defend two indefensible things: No. 1, statements by people, by Kate Michelman, that are absolutely erroneous and absolutely misguided. So she has no way to defend those statements. And then, in the second thing, she has no way and really no civilized society can defend this procedure. So what's left is a quick dive of the head into the sand and let's just forget the facts and continue to hope that maybe this is some medical procedure that is designed to handle this situation where a profoundly deformed child and all of that that we've heard so much about—forgetting all of the facts, forgetting all of the testimony that we've heard earlier on this bill.

And I wouldn't ask this panel to comment on this because they're not here to testify about that, but that testimony from people who do this, who admitted that this is not about profoundly deformed children, this is about a birth control technique. This is about an easy way that they see to exterminate children.

Mrs. SCHROEDER. Would the gentleman yield?

Mr. INGLIS. I'd be happy to. If you want to defend it, I think it's indefensible, but try if you will, one more time to see if——

Mrs. SCHROEDER. I do not believe—I mean, I think if you want to try Kate Michelman, she should be allowed to be here to defend herself, or whatever. But the issue of it being birth control, that is absolutely a——

Mr. INGLIS. Reclaiming my time on that—I'd be happy to yield to the chairman of the committee, because here is another misinformation, but it should be countered.

Mr. CANADY. The gentleman has yielded to me. Let's make very clear that we offered to the minority the opportunity to have any witness that the minority wished to have here today.

Mrs. SCHROEDER. The minority would like to have this hearing be on assault weapons ban which is up tomorrow.

Mr. CANADY. Will the gentlelady please suspend?

The minority refused to produce any witness that would testify on the medical issues that are the subject of today's hearing. Now you have put some letters in the record. I have not had the opportunity to review them, but I understand that there's not anything in any of those letters that challenges the statements that have been made here today by these expert witnesses concerning the effect of anesthesia administered to a pregnant woman on the child.

Now what I want to know, what I am concerned about, is: why, if there's another side to be told here, why witnesses were not produced? We asked for them. We invited witnesses, but they elected not to come. The minority did not provide them. We decided that we would not attempt to compel people to be here. We could have done that, I suppose, but I don't think that that would be in order.

If there's a case to be defended here, the proponents of that case, the people who have been spreading this misinformation, the people who have continued to spread this misinformation after undisputed medical authorities have testified to the contrary, those people simply did not want to show up because they know that what they've said cannot be defended. Now I think the way to handle that, if it was a mistake, admit a mistake. Say, "We were wrong." Say that there was an error, "We misunderstood." That "We had bad information." That would be the responsible thing to do. That's true not just in this controversy, but in other controversies. I think that, particularly in public controversies such as this, when there's a mistake made, it is incumbent upon those who have put out information that endangers people to correct that.

And the gentleman's time has expired.

Mrs. SCHROEDER. Mr. Chairman.

Mr. CANADY. The gentleman's time has expired.

I understand that there are a series of votes pending on the House floor.

Mrs. SCHROEDER. So we won't get to our panel, the witnesses that we did get here. Right?

Mr. CANADY. Oh, no, we most certainly are going to get to that panel, yes.

There are votes that are coming, and the committee will stand in recess. The committee will return, and the committee will reconvene at 1:30 this afternoon.

Mr. HYDE. Do you want to release these witnesses?

Mr. CANADY. Yes.

Mrs. SCHROEDER. What?

Mr. CANADY. Thank you. I again want to thank the members of this panel.

Mrs. SCHROEDER. Mr. Chairman, Mr. Chairman. First of all, I object to that. There are no votes going on right now. And our witnesses are here——

Mr. CANADY. The committee is in recess. The Chair is informed——

Mrs. SCHROEDER. You just went into a tirade about how we didn't have any witnesses. We've got witnesses here.

Mr. CANADY. The chairman will be back, and we will hear from the witnesses. The chairman most certainly wants to hear from all the witnesses who are here.

Mrs. SCHROEDER. Well, Mr. Chairman, I hope over the 2 hours you also read the 100-page opinion put in by the tricourt that tried these issues in the State of Ohio. I mean this is political theater. This not a trial court, and yet the gentleman is trying to have trials and play these things.

Mr. CANADY. This is not a trial court. This is a committee that is now in recess.

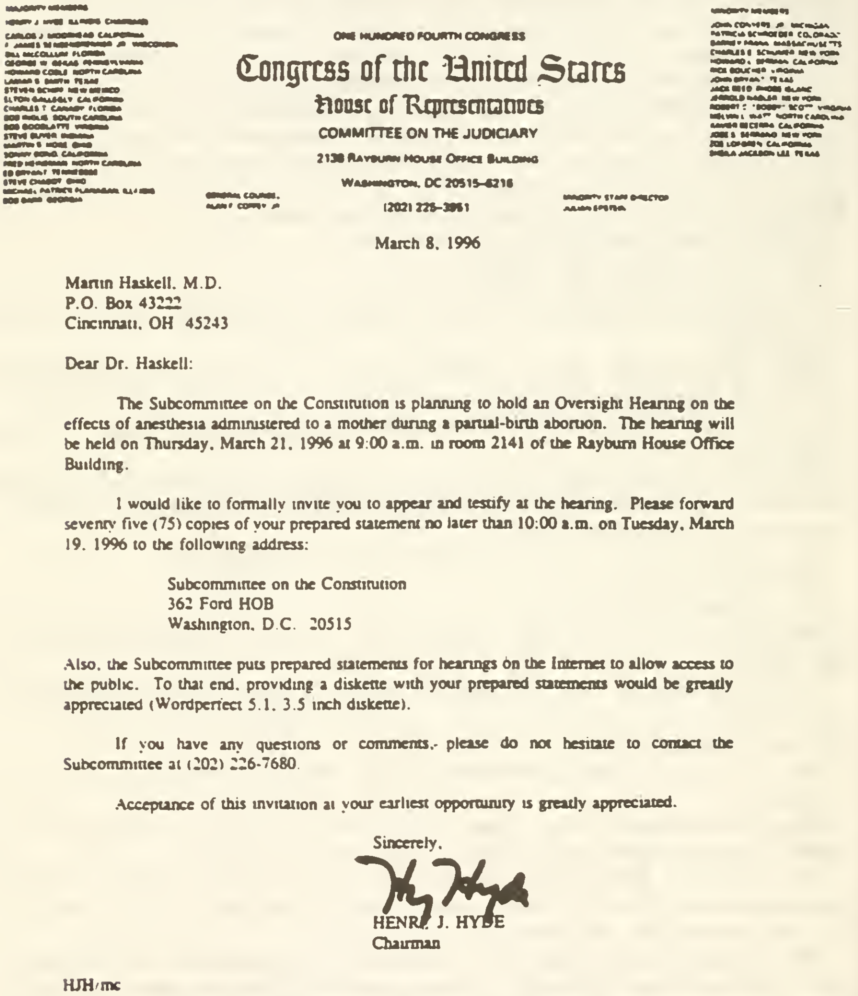
[Whereupon, at 11:31 a.m., the subcommittee recessed to reconvene at 1:30 p.m., the same day.]

[AFTERNOON SESSION]

Mr. CANADY. The subcommittee will be in order.

Without objection, I'd like to insert several items into the record: the letters of invitation to Dr. Haskell and Kate Michelman, the letter from Kate Michelman regarding this hearing, my letter to the ranking member of this subcommittee, and the "dear colleague" letter addressing the Ohio court decision.

[The information follows:]



ONE HUNDRED FOURTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 Rayburn House Office Building
Washington, DC 20515-6216
(202) 225-3951

March 8, 1996

Martin Haskell, M.D.
P.O. Box 43222
Cincinnati, OH 45243

Dear Dr. Haskell:

The Subcommittee on the Constitution is planning to hold an Oversight Hearing on the effects of anesthesia administered to a mother during a partial-birth abortion. The hearing will be held on Thursday, March 21, 1996 at 9:00 a.m. in room 2141 of the Rayburn House Office Building.

I would like to formally invite you to appear and testify at the hearing. Please forward seventy five (75) copies of your prepared statement no later than 10:00 a.m. on Tuesday, March 19, 1996 to the following address:

Subcommittee on the Constitution
362 Ford HOB
Washington, D.C. 20515

Also, the Subcommittee puts prepared statements for hearings on the Internet to allow access to the public. To that end, providing a diskette with your prepared statements would be greatly appreciated (Wordperfect 5.1, 3.5 inch diskette).

If you have any questions or comments, please do not hesitate to contact the Subcommittee at (202) 226-7680.

Acceptance of this invitation at your earliest opportunity is greatly appreciated.

Sincerely,

Henry Hyde

HENRY J. HYDE
Chairman

HJH/mc

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ALAN F COFFEY JR

MINORITY STAFF DIRECTOR
JULIAN EPSTEIN

March 8, 1996

Kate Michelman
President
National Abortion Rights
  Action League
1156 15th Street, N.W.
Washington, D.C. 20005

Dear Ms. Michelman:

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Acceptance of this invitation at your earliest opportunity is greatly appreciated.

Sincerely,

Henry Hyde

HENRY J. HYDE
Chairman

HJH/mc

NARAL Promoting Reproductive Choices

March 15, 1996

The Honorable Henry J. Hyde
Chairman
Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Hyde:

Thank you for offering me the opportunity to testify on March 21, 1996 before the Subcommittee on the Constitution.

I regret that I will be unable to testify before the Subcommittee due to a previous commitment located outside of the District of Columbia.

Sincerely,

Kate Michelman

Kate Michelman

cc: The Honorable Barney Frank

[illegible]

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ZOE LOFGREN, CALIFORNIA
SHEILA JACKSON LEE, TEXAS

March 19, 1996

The Honorable Barney Frank
Ranking Member
Subcommittee on the Constitution
2210 Rayburn H.O.B.
Washington, D.C. 20515

Dear Barney:

My staff has just informed me that the minority has not requested that any medical experts be invited to testify on the effects of anesthesia during a partial-birth abortion, the subject of Thursday's hearing before the Subcommittee on the Constitution.

As you know, the claim that anesthesia administered to a mother kills her unborn child before a partial-birth abortion has begun has been disseminated throughout the country by Kate Michelman of the National Abortion Rights Action League, Dr. Mary Campbell of Planned Parenthood, and the National Abortion Federation. Planned Parenthood and the National Abortion Federation represent hundreds of abortion providers. Surely one of their experts is willing to defend their claims. I find it disturbing that there is not a single medical expert to defend this claim which has been so prominent in the attacks on H.R. 1833.

In accordance with Committee procedures, I expect that I will receive the testimony of the minority's witnesses today. If you are able to find a witness with medical credentials, I would be happy to extend the deadline for that witness's testimony to 10:00 a.m. tomorrow.

Sincerely yours,

Chas.

Charles T. Canady
Chairman
Subcommittee on the Constitution

Congress of the United States
House of Representatives
Washington, DC 20515

March 18, 1996

H.R. 1833 is Constitutional

Dear Colleague:

In a March 11 letter five of our colleagues cited an Ohio abortion case as proof that H.R. 1833, the Partial-Birth Abortion Ban Act, is unconstitutional. Even if the dubious reasoning of the Ohio court withstands an appeal, the decision has no bearing on H.R. 1833.

The Ohio bill attempted to ban "Dilation and Extraction (D&X)" or "Brain Suction" abortions. A district court judge found that the definition of the abortion technique was vague because there are several abortion techniques that use suction, and therefore, an abortionist might not have sufficient notice as to which technique was actually banned.

H.R. 1833 does not ban "D&X" or "Brain Suction" abortions. H.R. 1833 bans any "abortion in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery." The ban would have the effect of prohibiting any abortion in which a child was partially delivered and then killed -- no matter what the abortionist decides to call his particular technique.

Roe v. Wade declared that "unborn" children were not persons under our Constitution, but the decision left intact a Texas statute that outlawed killing a partially born child. We are not considering the fate of unborn children in H.R. 1833. We are considering how our country will treat babies who are in the process of emerging from the womb.

But even if we considered these partially-born children to be non-persons, H.R. 1833 is constitutional under *Planned Parenthood v. Casey* because the ban does not place an "undue burden" on a woman's "right to choose" whether to have an abortion. There are a number of more widely used abortion techniques in both the second- and third-trimester of pregnancy. Even President Clinton, who has threatened to veto H.R. 1833, did not argue in his letter to the House and Senate Judiciary Committee Chairmen that the ban places an "undue burden" on women.

Regarding the issue whether a "health" exception is required, the Ohio case discusses this type of exception in the context of a ban on all third-trimester abortions. The discussion would not apply to a ban on a particular type of abortion. Even if the discussion did apply, H.R. 1833 allows any abortion in which the abortionist does not partially deliver the child alive before killing the child to be performed for "health" reasons. Inserting a "health" exception in H.R. 1833 would allow an abortionist to kill a child in the process of delivery for -- as the judge in the Ohio decision asserts -- both psychological and emotional reasons.

Opponents of H.R. 1833 cloak themselves in the mantle of *Roe v. Wade*, but even the *Roe* Court explicitly rejected the argument that the right to an abortion is absolute. The Court clearly stated that there is no right that entitles a woman "to terminate her pregnancy at whatever time, in whatever way, and for whatever reason she alone chooses."

Our five colleagues on the Judiciary Committee are still missing the point of the Partial-Birth Abortion Ban Act. Let us be clear: in H.R. 1833, we are protecting children from having their lives taken while being delivered from their mother's womb. As a civilized society we can do no less.

Sincerely yours,

Chas. T. Canady
Charles T. Canady

Henry J. Hyde
Henry J. Hyde

Bob Inglis
Bob Inglis

Michael P. Flanagan

Jim Sensenbrenner
F. James Sensenbrenner, Jr.

Martin R. Hoke
Martin R. Hoke

Mr. CANADY. We're now going to go to our third panel. I apologize for the fact that the proceedings on the floor of the House have delayed our resumption of the hearing and it just totally interfered with our proceeding.

Mrs. SCHROEDER. Could the record show we're 25 or 27 minutes after the last vote ended, Mr. Chairman?

Mr. CANADY. I don't think that's—I don't think that's accurate, but——

Mrs. SCHROEDER. I think it is; we've been watching the clock here.

Mr. CANADY. Well, there was a pending matter on the floor in which there was a vote anticipated.

For our final panel, we will hear testimony from Ms. Brenda Pratt Shafer. Ms. Shafer is a registered nurse who witnessed Dr. Michael Haskell of Ohio performing partial-birth abortions.

Next to testify will be Ms. Coreen Costello. Ms. Costello had an abortion performed by Dr. James McMahon of California.

Then we will hear from Ms. Mary-Dorothy Line. Ms. Line also had an abortion performed by Dr. McMahon.

Our last witness for today is Ms. Helen Alvaré, the Director of Planning and Information for Pro-Life Activities at the National Conference of Catholic Bishops.

Without objection, your full statements will be made a part of the record. I would like to ask that each of you summarize your testimony in five minutes or less. Thank you very much. We appreciate each of you taking the time to be with us today.

Ms. Shafer.

STATEMENT OF BRENDA PRATT SHAFER, REGISTERED NURSE, FRANKLIN, OH

Ms. SHAFER. Mr. Chairman and honorable members of the Judiciary Committee, I am Brenda Pratt Shafer. I am here before you at the request of the committee to relate to you my experience as an eyewitness to what is now known as the partial-birth abortion procedure. I'm a registered nurse licensed in the State of Ohio with 14 years of experience.

In 1993, I was employed by Kimberly Quality Care, a nursing agency in Dayton, OH. In September 1993, Kimberly Quality Care asked me to accept an assignment at the Women's Medical Center, which is operated by Dr. Martin Haskell. I readily accepted the assignment because I was at that time very pro-choice. I had even told my teenaged daughters that if one if them got pregnant at an early age, I would make them have an abortion. They disagreed with me on this, and one of them even wrote an essay for a high school class that mentioned how we differed on the issue. So because of the strong pro-choice views that I held at that time, I thought this assignment would be no problem for me, but I was wrong.

I stood at a doctor's side as he performed the partial-birth abortion procedure, and what I saw is branded on my mind forever. I worked as an assistant nurse at Dr. Haskell's clinic for 3 days, September 28, 29, and 30 of 1993. On the first 2 days I observed and assisted women who were there for first-trimester abortions, and for second-trimester abortions other than the partial-birth abortions.

Also on the first 2 days, we inserted laminaria to dilate the cervixes of women who were being prepared for the partial-birth abortions. They were the women who were past the 20 weeks point, or 4½ months. Dr. Haskell called this procedure "D&X" for "dilation and extraction." There were six or seven of these women.

On the third day Dr. Haskell asked me to observe as he performed several of the procedures that are the subject of this hearing. Although I was in that clinic on assignment from the agency, Dr. Haskell was interested in hiring me full time, and I was being given orientation in the entire range of procedures provided at that facility. I was present for three of these partial-birth procedures. It is the first one, though, I describe to you in detail.

The mother was 6 months pregnant, 26½ weeks. A doctor told her that her baby had Down Syndrome, and she decided to have an abortion. She came in the first 2 days to have the laminaria inserted and changed, and she cried the whole time. On the third day she came in to receive the partial-birth abortion.

Dr. Haskell brought the ultrasound in and hooked it up, so that he could see the baby. I could clearly see the baby's heartbeat on the ultrasound screen. Mr. Chairman, this is a medical school model of an unborn baby, just a little bit smaller than the baby who I was looking at that day.

Dr. Haskell went in with forceps and grabbed the baby's legs and pulled them down into the birth canal. Then he delivered the baby's body and arms—everything but the head. The doctor kept the baby's head just inside the uterus.

The baby's little fingers were clasping and unclasping, and his feet were kicking. Then the doctor stuck the scissors through the back of his head, and the baby's arms jerked out in a flinch, a startle reaction, like a baby does when you throw him up in the air and he thinks he might fall. The doctor opened up the scissors, stuck a high-powered suction tube into the opening, and sucked the baby's brains out. Now the baby went completely limp.

I was really completely unprepared for what I was seeing. I almost threw up as I watched the doctor do these things.

Mr. Chairman, I read in the paper that President Clinton says he's going to veto this bill. If President Clinton had been standing where I was standing at that moment, he would not veto this bill.

Dr. Haskell delivered the baby's head. He cut the umbilical cord and delivered the placenta. He threw that baby in a pan, along with the placenta and the instruments he used. I saw the baby move in the pan, and I asked another nurse and she said it was just "reflexes."

I have been a nurse for a long time and I have seen a lot of death—people maimed in automobile accidents, gunshot wounds, you name it. I have seen surgical procedures of every sort. But in all my professional years I had never witnessed anything like that.

The woman wanted to see her baby, so they cleaned the baby up and put it in a blanket and handed the baby to her. She cried the whole time. Looking down into the baby's face, she said, "Please forgive me. I am so sorry. I love you." I was crying, too. I couldn't take it. That baby boy had the most perfect angelic face you've ever seen.

I was present in the room during two more such procedures that day, but I think I was really in shock. I tried to pretend that I was somewhere else, to not think about what was happening. I just couldn't wait to get out of there. And after I left that day, I never went back. These last two procedures, by the way, involved healthy mothers with healthy babies.

I was very much affected by what I had seen.

Mr. CANADY. I'm sorry, the time has expired. If you could try to conclude as soon as possible——

Ms. SHAFER. Yes. And for a long time I still, and still do, had nightmares about what I saw that day. And that's when I wrote a letter to Congressman Tony Hall last July and told him about what I had seen.

Since I wrote that letter to Congressman Tony Hall, I have been the subject of some strange attacks on my credibility. These are addressed point by point in my written testimony. There are people who say I haven't seen what I've seen. I wish that was true. I wish I hadn't seen it, because I don't like being here to tell you today, but it is true, and what was done to that little boy and to other babies should not be allowed in this country.

[The prepared statement of Ms. Shafer follows:]

PREPARED STATEMENT OF BRENDA PRATT SHAFER, REGISTERED NURSE, FRANKLIN, OH

Mr. Chairman and honorable members of the Judiciary Committee, I am Brenda Pratt Shafer. I am here before you, at the request of the Committee, to relate to you my experience as an eyewitness to what is now known as the partial-birth abortion procedure.

I am a registered nurse, licensed in the State of Ohio, with 14 years of experience. In 1993, I was employed by Kimberly Quality Care, a nursing agency in Dayton, Ohio. In September, 1993, Kimberly Quality Care asked me to accept assignment at the Women's Medical Center, which is operated by Dr. Martin Haskell. I readily accepted the assignment because I was at that time very pro-choice. I had even told my teenager daughters that if one of them ever got pregnant at a young age, I would make them get an abortion. They disagreed with me on this, and one of them even wrote an essay for a high school class that mentioned how we differed on the issue.

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But I was wrong. I stood at a doctor's side as he performed the partial-birth abortion procedure—and what I saw is branded forever on my mind.

I worked as an assistant nurse at Dr. Haskell's clinic for three days—September 28, 29, and 30, 1993.

On the first day, we assisted in some first-trimester abortions, which is all I'd expected to be involved in. (I remember that one of the patients was a 15-year-old-girl who was having her third abortion.)

On the second day, I saw Dr. Haskell do a second-trimester procedure that is called a D & E (dilation and evacuation). He used ultrasound to examine the fetus. Then he used forceps to pull apart the baby inside the uterus, bringing it out piece by piece and piece, throwing the pieces in a pan.

Also on the first two days, we inserted laminaria to dilate the cervixes of women who were being prepared for the partial-birth abortions—those who were past the 20 weeks point, or 41/2 months. (Dr. Haskell called this procedure "D & X", for dilation and extraction.) There were six or seven of these women.

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I was present for three of these partial-birth procedures. It is the first one that I will describe to you in detail.

The mother was six months pregnant (26½ weeks). A doctor told her that the baby had Down Syndrome and she decided to have an abortion. She came in the first two days to have the laminaria inserted and changed, and she cried the whole time. On the third day she came in to receive the partial-birth procedure.

Dr. Haskell brought the ultrasound in and hooked it up so that he could see the baby. On the ultrasound screen, I could see the heart beating. As Dr. Haskell watched the baby on the ultrasound screen, the baby's heartbeat was clearly visible on the ultrasound screen.

Dr. Haskell went in with forceps and grabbed the baby's legs and pulled them down into the birth canal. Then he delivered the baby's body and the arms—everything but the head. The doctor kept the baby's head just inside the uterus.

The baby's little fingers were clasping and unclasping, and his feet were kicking. Then the doctor stuck the scissors through the back of his head, and the baby's arms jerked out in a flinch, a startle reaction, like a baby does when he thinks that he might fall.

The doctor opened up the scissors, stuck a high-powered suction tube into the opening and sucked the baby's brains out. Now the baby was completely limp.

I was really completely unprepared for what I was seeing. I almost threw up as I watched the doctor do these things.

Mr. Chairman, I read in the paper that President Clinton says that he is going to veto this bill. If President Clinton had been standing where I was standing at that moment, he would not veto this bill.

Dr. Haskell delivered the baby's head. He cut the umbilical cord and delivered the placenta. He threw that baby in a pan, along with the placenta and the instruments he'd used. I saw the baby move in the pan. I asked another nurse and she said it was just "reflexes."

I have been a nurse for a long time and I have seen a lot of death—people maimed in auto accidents, gunshot wounds, you name it. I have seen surgical procedures of every sort. But in all my professional years, I had never witnessed anything like this.

The woman wanted to see her baby, so they cleaned up the baby and put it in a blanket and handed the baby to her. She cried the whole time, and she kept saying, "I'm so sorry, please forgive me!" I was crying too. I couldn't take it. That baby boy had the most perfect angelic face I have ever seen.

I was present in the room during two more such procedures that day, but I was really in shock. I tried to pretend that I was somewhere else, to not think about what was happening. I just couldn't wait to get out of there. After I left that day, I never went back. These last two procedures, by the way, involved healthy mothers with healthy babies.

I was very much affected by what I had seen. For a long time, sometimes still, I had nightmares about what I saw in that clinic that day.

That's why, last July, I wrote a letter to Congressman Tony Hall of Dayton, in support of the bill, telling what I had seen. And that led to me being asked to tell others what I'd seen, just as I am doing here today.

Mr. Chairman, since I wrote that letter to Congressman Tony Hall, I have been subjected to some strange attacks on my credibility, and I would like to address these briefly.

Last July 12, I sat in the audience as the full Judiciary Committee debated this legislation, and I heard Congresswoman Schroeder read a letter from Dr. Haskell to the Judiciary Committee (also dated July 12) in which he said, "I have examined our records and found no evidence of a Brenda Shafer working for us during 1993."

Fortunately, I had previously provided the Constitution Subcommittee with the pertinent payroll records from Kimberly Quality Care, including their invoice to Dr. Haskell's clinic. After these documents were circulated, Congresswoman Schroeder withdrew that particular allegation, explaining it away as resulting from confusion over my married name. But it seemed peculiar to me at the time that neither she nor her staff had contacted me, or the subcommittee staff, to request documentation, before she basically called me a liar in front of everybody. But there was much more of that sort of thing to come.

In his July 12 letter, Dr. Haskell said also said that my account was "inaccurate," because "she describes procedures at 26½ weeks and 25 weeks. . . . This is contrary to my own self-imposed and established limit of 24 weeks." But in recent times I've seen an article published in American Medical News for July 5, 1993—just a few months before I worked for him—in which Dr. Haskell said that he performs the procedure "up until about 25 weeks," which conflicts with his letter to the Judiciary Committee.

Also, in Dr. Haskell's 1992 paper describing the partial-birth procedure, "Dilation and Extraction for Late Second Trimester Abortion," which you have all seen, he wrote, "This author routinely performs this procedure on all patients 20 through 24 weeks LMP [i.e., from last menstrual period] with certain exceptions. The author performs the procedure on selected patients 25 through 26 weeks LMP." Keep in mind that this 26½-week little boy had Down syndrome, so this was a "selected patients" case.

Later, I learned another letter had been produced by Dr. Haskell's operation, dated July 17, this one signed by Christie Gallivan, a nurse. This letter was cited by opponents of the bill before and during the House and Senate floor debates, and was even entered into the *Congressional Record* by Senator Barbara Boxer.

In this letter, Christie Gallivan acknowledged that I had worked at the clinic for three days, but went on to claim that since I was a temporary nurse, I "would not have been present" at such a procedure—or, then again, in the alternative, that if I *did* see such a procedure, then my memory must be faulty, or else that I must be deliberately "misrepresenting" what I saw.

Well, as I've said from the beginning, although I was assigned by a temporary agency, Dr. Haskell needed another surgical nurse—I was told that he was having a hard time keeping them—and he seemed to be interested in hiring me on a permanent basis. He wanted me to observe the procedure.

Christie Gallivan was the surgical nurse and she spent those three days giving me an "orientation," as it says on the Kimberly Quality Care invoice. But what is striking to me is how blatantly inconsistent Nurse Gall Ivan's letter is, not only with what I saw, but with what Dr. Haskell himself has written and said elsewhere.

Christie Gallivan wrote, "Dr. Haskell does not use ultrasound in the performance of second-trimester procedures." Then she went on, regarding my account, "Therefore, her entire description of her experience with viewing the second-trimester abortion, which includes Dr. Haskell using the ultrasound while doing this procedure, is clearly questionable."

Yet, in Dr. Haskell's paper explaining how he performs the procedure, he clearly states that the surgical assistant "places an ultrasound probe on the patient's abdomen and scans the fetus, locating the lower extremities." And a little further on, referring to the forceps, he wrote, "When the instrument appears on the sonogram screen, the surgeon is able to open and close its jaws to firmly and reliably grasp a lower extremity."

So when Christie Gallivan writes that I could not have seen a baby moving, you can evaluate that statement in the light of her other statements on these points on which there is such a clear written record. And, you should notice that she never tries to explain, in this letter, why anyone should believe that these babies supposedly don't move. I've been given a copy of a transcript of the tape-recorded interview with Dr. Haskell conducted by the American Medical News in June, 1993—only three months before my time at his clinic—in which he explicitly acknowledged that most of these babies are alive when he pulls them out.

On November 17, I testified before the Senate Judiciary Committee. Senator Kennedy asked me why it had been reported in a nursing newsletter, that I was employed by the National Right to Life Committee. As replied, and I tell you know, I've never been a member of, or a donor to, that organization, and certainly in no sense an employee.

Certainly, since last summer I have cooperated with National Right to Life in their efforts to make my experience more widely known, because I think it's important that people know the truth about this matter. But National Right to Life has not paid me for anything, and nobody else has paid me for anything in connection with this subject either, beyond reimbursing travel and accommodation expenses. By the way, the editor of the nursing newsletter subsequently retracted the erroneous claim.

Most recently, I got a copy of a letter sent to a constituent by Congresswoman Lynn Rivers of Michigan, written in longhand, in which this distinguished member of Congress claimed that I "was unwilling to testify under oath or submit herself to cross examination in front of Congress—even though she was sitting in the hearing room while testimony was being taken."

Of course, Mr. Chairman, that is all pure fiction. By the time I heard of your bill and wrote my letter to Congressman Hall, on July 9, you had already concluded the hearing on your legislation. I was present for the July 12 markup, and spoke with various members of the committee and the press informally, but of course there was no opportunity for me to formally testify on that occasion, although I certainly would have welcomed the opportunity.

In November, when Senator Hatch invited me to testify before the Senate Judiciary Committee, I accepted immediately and without qualification. During the question period, Senator Kyle asked me if I would be willing to testify to these things under oath and I replied, "Yes, sir, I would. Or under a lie detector or anything else I need to do." [Senate hearing record, p. 63.] And I tell you the same thing.

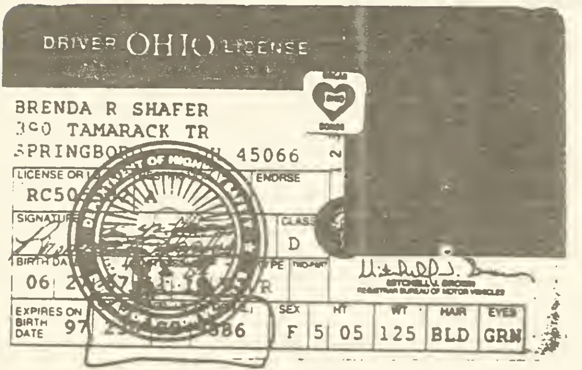
Mr. Chairman, thank you for indulging me in unburdening myself on these points. It is been frustrating to hear, and hear of, these attacks on my truthfulness, and not be able to respond.

It is still amazing to me that certain individuals who hold high elective offices, offices for which I hold great respect, have been so willing to publicly spread this kind of blatant misinformation about me, without making the slightest effort to investigate or look at any of the documentation.

Mr. Chairman, these people who say I didn't see what I saw—I wish they were right. I wish I hadn't seen it. But I did see it, and I will never be able to forget it. That baby boy was only inches, seconds away from being entirely born, when he was killed. What I saw done to that little boy, and to those other babies, should not be allowed in this country.

Thank you.

Pratt is Brenda Shafer's maiden name. Below are her social security number and RN license number listed on her Ohio driver's license and Ohio Board of Nursing card, respectively. Both numbers are listed on the bill submitted by the nursing agency to Dr. Haskell's clinic. Nurse Shafer worked as an assistant nurse at Dr. Haskell's abortion clinic for three days in September, 1993, an experience she described in a letter to Congressman Tony Hall and in the attached testimony.



DRIVER OHIO LICENSE

BRENDA R SHAFER
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SPRINGBO[illegible]H 45066

LICENSE OR [illegible] ENDORSE
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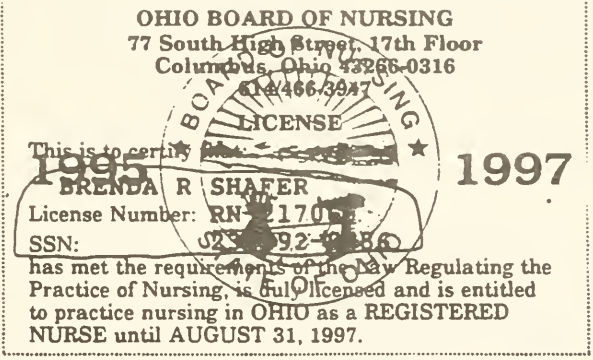


OHIO BOARD OF NURSING
77 South High Street, 17th Floor
Columbus, Ohio 43266-0316
614/466/3947

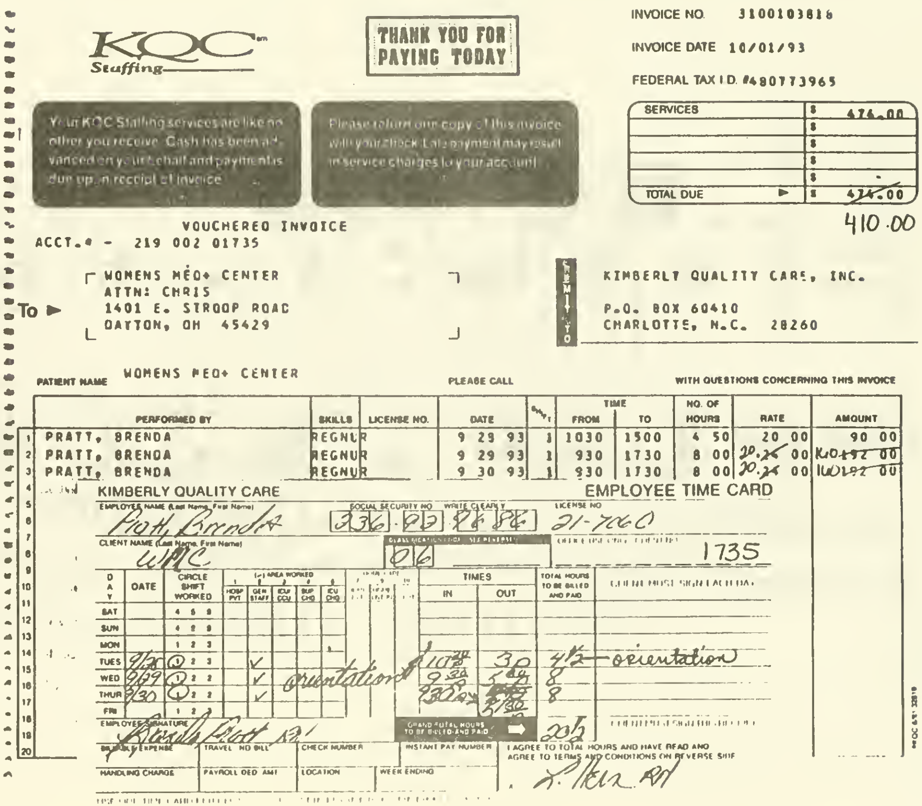
LICENSE

This is to certify [illegible]

1995 1997

BRENDA R SHAFER
License Number: RN-2170[redacted]
SSN: [redacted]

has met the requirements of the Law Regulating the Practice of Nursing, is duly licensed and is entitled to practice nursing in OHIO as a REGISTERED NURSE until AUGUST 31, 1997.



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CHARLOTTE, N.C. 28260

PATIENT NAME WOMENS MED+ CENTER

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	PERFORMED BY	SKILLS	LICENSE NO.	DATE	SHIFT	TIME FROM	TIME TO	NO. OF HOURS	RATE	AMOUNT
1	PRATT, BRENDA	REGNUR		9 29 93	1	1030	1500	4 50	20 00	90 00
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3	PRATT, BRENDA	REGNUR		9 30 93	1	930	1730	8 00	20. ~~24~~ 00	160 ~~192~~ 00

KIMBERLY QUALITY CARE — EMPLOYEE TIME CARD

EMPLOYEE NAME (Last Name, First Name): Pratt, Brenda

SOCIAL SECURITY NO. WRITE CLEARLY: 336-92-9886

LICENSE NO: 21-7060

CLIENT NAME (Last Name, First Name): WMC

CLASSIFICATION CODE: 06

1735

DAY	DATE	CIRCLE SHIFT WORKED	(✓) AREA WORKED GEN STAFF		TIMES IN	TIMES OUT	TOTAL HOURS TO BE BILLED AND PAID	
SAT		4 5 9						
SUN		4 2 9						
MON		1 2 3						
TUES	9/28	[✓ 1] 2 3	✓	orientation	10 30	3 00	4½	orientation
WED	9/29	[✓ 1] 2 2	✓		9 30	5 30	8	
THUR	9/30	[✓ 1] 2 2	✓		930	5 30	8	
FRI		1 2 3						

EMPLOYEE SIGNATURE: Brenda Pratt RN

GRAND TOTAL HOURS TO BE BILLED AND PAID ➡ 20½

BILLABLE EXPENSE / TRAVEL NO BILL / CHECK NUMBER / INSTANT PAY NUMBER

HANDLING CHARGE / PAYROLL DED AMT / LOCATION / WEEK ENDING

I AGREE TO TOTAL HOURS AND HAVE READ AND AGREE TO TERMS AND CONDITIONS ON REVERSE SIDE

L. Klein RN

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*** CRITICAL ***                                                                                          *** CRITICAL ***

PYRG35      10/06/93                              KIMBERLY QUALITY CARE                               PERIOD ENDING 10/01/93
PAGE    17                                  P A Y R O L L   R E G I S T E R                              PAY DATE 10/08/93
CO/DIV:  219-002                                KIMBERLY QUALITY CARE, INC.

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THE WOMEN'S MEDICAL CENTER,
Dayton, July 17, 1995.

DEAR CONGRESSWOMAN SCHROEDER: I am a registered nurse and have worked since July, 1993, in the Dayton office of Dr. Martin Haskell. In this capacity, I was the nurse that supervised the training of Brenda Pratt during her brief temporary employment at the Women's Medical Center of Dayton. As you know, we initially conducted a search of our employment records under the name "Brenda Shafer," as this was the name she signed to the letter which was given to us. When provided with the correct last name, we did in fact find the record of her three-day employment at our Dayton facility.

The information provided by Ms. Pratt as to our practices at the Women's Medical Center of Dayton is largely inaccurate. First, she describes Dr. Haskell performing one 25-week and one 26-week abortion procedure. Dr. Haskell does not perform abortions past 24 weeks of pregnancy. This is a self-imposed limit to which he has scrupulously adhered throughout the time I have worked for him.

Second, Dr. Haskell does not use ultrasound in the performance of second-trimester procedures. We use ultrasound only to determine the pregnancy's gestation. Therefore, her entire description of her experience when viewing a second-trimester abortion, which includes Dr. Haskell's using the ultrasound while doing the procedure, is clearly questionable.

Finally, at no point during a dilatation and extraction or intact D&E is there any fetal movement or response that would indicate awareness, pain or struggle. Ms. Pratt absolutely could not have witnessed fetal movement as she describes. We do not train temporary nurses in second trimester dilatation and extraction, since it is a highly technical procedure and would not be performed by someone in a temporary capacity. If, indeed, Ms. Pratt entered the operating room at any point during D&X procedure, she clearly either is misrepresenting what she saw or remembers it incorrectly.

If you have any further questions, please feel free to contact our office.

Sincerely,

CHRISTIE GALLIVAN, RN.

Mr. CANADY. Thank you, Ms. Shafer.

Mrs. Costello.

STATEMENT OF COREEN COSTELLO, AGOURA, CA

Ms. COSTELLO. I want to thank you for allowing me to testify here today. I want to make it clear that I am not a political activist. I have no political agenda here today. What I am is a patient of the procedure that you are trying to ban.

My name is Coreen Costello. I live in Agoura, CA, with my husband Jim, my son Chad, and my daughter Carlyn. Someone has kindly put up a picture of my family. I'm very proud of my children.

Jim is a chiropractor, and I love being a full-time wife and mother. I am a registered Republican and very conservative. I do not believe in abortion. Because of my deeply-held Christian beliefs, I knew I would never have an abortion. In fact, I remember a few years ago when I was nursing my son Chad late in the evening—it was in the middle of the night—I was watching C–SPAN, and I actually caught Senator—or Congressman Hyde speaking on abortion, and you moved me quite deeply. It was very eloquent.

Even now, I am amazed at the fact that I am here. I would never have believed that I, with my profound belief in the rights, value, and sanctity of the unborn, would be here in support of an abortion procedure.

After my first two children, my third pregnancy tragically was ectopic, causing my tube to rupture and requiring major emergency surgery. We grieved the loss of that child. We were especially overjoyed and relieved when my fourth pregnancy was in the right place and seemed to be going well. Then on March 24, almost a year ago to this day, when I was 7 months pregnant, just as I am now, the premature contractions I had been experiencing became harder and faster, and my husband I rushed to the hospital.

During an ultrasound, the physician became very silent. Soon more physicians came in. They, too, were silent. My husband told me everything would be OK. I knew there was something terribly wrong. I went into the bathroom and I sobbed. I begged God to let my baby be OK. I prayed like I had never ever prayed before in my life.

My husband reassured me that we could deal with whatever was wrong. We had talked about raising a child with disabilities. There was never a question that we would take whatever God gave us.

My doctor arrived at 2 o'clock in the morning. He held my hand and informed me that they did not expect our baby to live. She was unable to absorb any amniotic fluid and it was puddling into my uterus. This was causing my contractions. This poor precious child had a lethal neurological disorder and had been unable to move for almost two months. The movements I had been feeling over the last months had been nothing more than bubbles and fluid. Her chest cavity was unable to rise and fall to stretch her lungs to prepare them for air. It was as if she had no lungs at all. Her vital organs were atrophying. Our darling little girl was dying.

A perinatalogist recommended terminating the pregnancy. For my husband and me, this was not an option. We chose—we made a choice and we chose—to go into labor naturally. We knew that it would not be long. Due to the excess amniotic fluid, a condition known as polyhydramnios, premature delivery was imminent. It was so difficult to go home and be pregnant knowing my baby was dying. I did not want to get out of bed.

My husband said to me, "Coreen, this baby is still with us. She's still alive. Let's make these last days of her life as special as possible." I put on my best maternity clothes and I went out. I felt her life inside of me, and somehow I still glowed. At this time we chose our daughter's name. We named her Katherine Grace—"Katherine" meaning pure and "Grace" representing God's mercy.

We went to many more experts over the next 2 weeks. It was discovered that Katherine's body was rigid and she was wedged in a transverse position. Most babies are in a fetal position, just as this baby is here. Katherine was the exact opposite. Her head was arched back. She was as if she was in a U-shape. Her body was stiff and rigid. Her head and the top of her feet were—the bottom of her feet were practically touching, and they were at the top of my uterus. Her tummy was over my cervix, and she was stuck and stiff. It broke my heart.

I did exercises—her head, another problem was that her head was swollen larger than that of a full-term baby. I did exercises every day trying to change Katherine's position, so that she could be delivered naturally. The amniotic fluid continued to puddle into my uterus.

No one expected her to survive labor, but if she had survived a natural birth or a C-section, we knew she would have suffocated immediately——

Mr. CANADY. If you could conclude as soon as possible——

Ms. COSTELLO. OK. I have quite a bit. Would someone yield to me a few minutes?

Mr. CANADY. I'm sure that Mrs. Schroeder will be happy to yield you additional time.

Ms. COSTELLO. Would that be possible?

Mrs. SCHROEDER. I would yield my 5 minutes of questioning, if the Chair's going to insist, yes.

Ms. COSTELLO. If that's—I know you're looking for the truth, and this is—I actually experienced this, sir.

Mr. CANADY. We're going to—you'll have an opportunity to make an additional comments you want to make. If you could try to wrap up what you're saying now——

Ms. COSTELLO. I'll do the best I can.

Mr. CANADY [continuing]. Then we'll get back to you.

Ms. COSTELLO. Anyway, we knew, had she been able to be delivered naturally or through cesarean, she would suffocate immediately. She had no lungs. She couldn't take even one breath.

More and more ultrasounds made that terrible truth clearer and clearer: that if she was born, her passing would not be peaceful or painless. We kept praying for a miracle, hoping that she would be able to pass away in my arms. I wanted her to hear me say that I loved her.

We went back to the hospital again and again, thinking I was in labor. We were completely prepared to bring her into the world with the hope of having her for just a moment. This was my mission, but this was not to be.

Each day she grew worse. So we had her baptized in utero——

Mr. CANADY. OK. We'll——

Ms. COSTELLO. I know, sir.

Mr. CANADY. We'll be happy to let you continue. We're going to go to Mrs. Line now. In fairness to——

Ms. COSTELLO. I'm so sorry, sir, you know, I just have to say something. Can I say something very quickly?

Mr. CANADY. Sure.

Ms. COSTELLO. I traveled all the way from California and I hate to fly. This is the truth. This is what happened to me. I think you owe it to us to at least hear this.

Mr. CANADY. Oh, sure. We will—we will certainly hear you.

Mrs. SCHROEDER. Mr. Chairman, if I gave up my five minutes and gave it to her now, could she please—I mean, she's——

Mr. CANADY. Certainly.

Mrs. SCHROEDER [continuing]. Been waiting since 9:30 this morning.

Mr. CANADY. Yes.

Mrs. SCHROEDER. And to break this story up makes no sense.

Thank you, Mr. Chairman.

Mr. CANADY. Certainly.

Ms. COSTELLO. We decides to baptize her in utero, while we knew she was still alive.

By this time, I had seen my own obstetrician, two resident obstetricians at Cedar Sinai, and four perinatalogists. Each of these doctors had consulted with other experts. The doctors all agreed that our safest option was an intact D&E. For Jim and me this remained not an option.

Finally, after 2½ weeks, I went to my own doctor again for another ultrasound. The polyhydramnios had grown even worse. I could not sit or lie down for more than 10 minutes because the pressure on my lungs was so great. My husband and our whole family were afraid for my health. Naively, I wasn't worried about myself; my only concern was Katherine.

When the doctors performed the ultrasound, Katherine's heart was barely beating. He turned to my husband and said, "I can't deliver this baby. I could try, but I am convinced we would end up doing a cesarean, and under the circumstances that is too dangerous." He said, "I have to send you to Dr. McMahon." I gasped out loud.

My doctor said to Jim, "This is about Coreen now." I began to cry. Again, I said, "What about a cesarean?"

He said, "I can't justify that risk to you. There is a safer way."

When I saw the anguish on my doctor's face, I knew we had no other choice. He had supported us in our decision to have Katherine naturally. He knew that we would have to live with our decision for the rest of our lives. This wasn't a choice anymore; it wasn't up to us. There was no reason to risk leaving my two children motherless if there was no hope of saving Katherine.

We drove to Dr. McMahon's clinic. I cried the whole way, patting my tummy, promising my little girl I would not let anyone hurt or devalue her. My husband was adamant, if we weren't comfortable, we would turn around; there was no way he would let his little girl's life end in a way that didn't give her respect and dignity. I never felt so scared and sick to my stomach. I kept asking God, "Why are you making this so difficult for us?"

We expected a cold, gray building. I expected an abortion mill. I expected people who possibly cared about me, but not about Katherine. When we arrived the place was nice and peaceful. When we walked in, I was still very defensive. I did not trust these people.

The staff greeted us with warmth and kindness. I was immediately taken in to see Gale McMahon, the clinic's head nurse. We started to talk, and Gale asked if we had named our baby. "Her name is Katherine Grace," I said, and I began to cry. When I looked up, she, too, had tears in her eyes. At that moment a little bit of my wall broke down.

Gale explained the procedure in detail.

I'm going to try to make this faster for you.

When I met with Dr. McMahon, he performed another ultrasound. He knew how much discomfort I was in. I can only tell you that he was gentle and kind.

Dr. McMahon immediately asked me the same question Gale had, "Have you named her?" He never referred to her as fetal tissue or a fetus or even just a baby. He called her "Katherine."

After Dr. McMahon explained the procedure to us again, I knew I was in the right place. This left open the possibility of more children. It greatly lowered my health risk. And, most important to me, it offered a peaceful passing for Katherine Grace.

When Dr. McMahon put in the first set of dilators, I went into labor and my water broke. I lost 9¾ pounds of fluid. When I was put under anesthesia, I was dilated sufficiently where they were able to perform the procedure.

When I awoke a few hours later, Katherine was brought into us. She was beautiful. She was not missing part of her brain. She had not been stabbed in the head with scissors. She looked peaceful. My husband and I held her tight and sobbed.

One of the things I noticed when I was holding Katherine was that the socks we bought for her were too big. Someone had taken tiny, soft pink ribbons and tied them gently at the ankles, so that her socks would fit. I can't tell you the peace that that brought me.

My husband and I stayed with her for hours. We sang. We held her. We prayed. Giving her back was the hardest moment of my life.

They offered counseling for our entire family, including our grandparents.

I'll wrap it up right now.

Mr. CANADY. Yes.

Ms. COSTELLO. Just give me 1 minute, please, and I'll wrap it up.

Because of the safety of this procedure, I am now pregnant again and will have another baby in June. Thanks to the grace of God and the safety of this medical procedure, I can have another healthy baby. If you outlaw this procedure, other women like me will be denied that gift, that joy. They may lose their ability to have more children. They may lose their health. They may lose their lives.

The child I carry today is by no means a replacement for Katherine. We will always miss her, and there will always be a hole in my heart where she belongs.

Mr. CANADY. You've had an additional 6 minutes. So if you could——

Ms. COSTELLO. I'm disappointed that you guys don't want to hear from us, but that's fine.

Mr. CANADY. Well, you know, we have given you about 12 minutes. Ms. Shafer had about 6 minutes.

Ms. COSTELLO. I appreciate that. Thank you.

Mr. CANADY. OK. There will be questions. So we'll have an opportunity then to hear from you further.

[The prepared statement of Ms. Costello follows:]

PREPARED STATEMENT OF COREEN COSTELLO, AGOURA, CA

My name is Coreen Costello. I live in Agoura, California, with my husband Jim and our son Chad and daughter Carlyn. Jim is a chiropractor and I love being a full-time, stay-at-home wife and mom. I am a registered Republican, and very conservative. I don't believe in abortion. Because of my deeply held Christian beliefs, I knew that I would never have an abortion. In fact, I remember a few years ago when I was nursing my son Chad, I watched a speech Congressman Hyde gave on C–SPAN against abortion. It was so eloquent, it moved me to tears. I even participated in the "Walk for Life" sponsored by our local Christian radio station.

Even now, I am amazed at the fact that I am here. I never would have believed that I would be testifying in Congress, supporting an abortion procedure.

In March of last year, we were joyfully expecting the arrival of our third child. Then on March 24, almost a year ago to the day, when I was seven months pregnant, I began having premature contractions and my husband and I rushed to the hospital.

During an ultrasound, the physician became very silent. Soon more physicians came in. Jim told me everytning would be fine but I knew there was something very wrong. I went into the bathroom and sobbed. I begged God to let my baby be okay. I prayed like I've never prayed before in my life.

My husband reassured me that we could deal with whatever was wrong. We had talked about raising a child with disabilities and there was never a question that we would take whatever God gave us.

My doctor arrived at two in the morning. He held my hand, and informed me that they did not expect our baby to live. She was unable to absorb the amniotic fluid and it was puddling into my uterus. This poor precious child had a lethal neurological disorder and had been unable to move for almost two months. The movements I had been feeling over the last few months had been nothing more than bubbles and fluid. Her chest cavity was unable to rise and fall to stretch her lungs to prepare them for air. It was as if she had no lungs at all. Her vital organs were atrophying. Our darling little girl was going to die.

A perinatologist recommended terminating the pregnancy. For my husband and me, this was not an option. We chose to wait to go into labor naturally. We knew that it would not be long. Due to the excess amniotic fluid, a condition called polyhydramnios, premature labor was imminent. I wanted her to come on God's time—I didn't want to interfere.

It was so difficult to go home and be pregnant and go on with life, knowing my baby was dying. I wanted to stay in bed. My husband looked at me and said, "Coreen, this baby is still with us. Let's be proud of her. Let's make these last days of her life as special as possible." I got out of bed and put on my best maternity clothes, and went out with my daughter Carlyn to get ready for her fifth birthday party. I could feel my baby's life inside of me, and somehow I still glowed. At this time we chose her name—Katherine Grace. "Katherine" meaning pure, and "Grace" representing God's mercy.

We went to many more experts over the next two weeks. It was discovered that Katherine's body was rigid and she was wedged in a transverse position. Most babies are in the fetal position, but Katherine's position was exactly the opposite. It was as if she were doing a swan dive—the soles of her feet were touching the back of her head. Her body was in a U-shape. Due to swelling, her head was already larger than that of a full-term baby. I did exercises every day, trying to change Katherine's position so that she could be delivered naturally. The amniotic fluid continued to puddle into my uterus.

No one expected her to survive labor, but if she had survived a natural birth or a C-section, we knew she would have suffocated immediately after the umbilical cord was cut. She had no lungs. She couldn't take even one breath. More and more ultra sounds made that terrible truth clearer and clearer, that if she were born, her passing would not be peaceful or painless. But we kept praying for a miracle, hoping that she would be able to pass away with our arms wrapped tightly around her, hearing us telling her how much we loved her.

We went back to the hospital again and again, thinking I was in labor. We were completely prepared to bring her into the world, with the hope of having her with us even just for a moment. This was my mission. But it was not to be. We decided to baptize her in utero, while we knew she was still alive.

By this time, I'd seen my own obstetrician, two resident obstetricians at Cedars-Sinai, and four perinatologists. Each of these doctors had consulted with other experts. The doctors all agreed that our safest option was an intact D&E, but Jim and I couldn't face the horrible thought of having an abortion.

Finally, after two and a half weeks, I went to my own doctor again for another ultrasound. The polyhydramnios had grown even worse and my husband and our whole family were afraid for my health. I could not sit or lie down for more than ten minutes because the pressure on my lungs was so great. But I wasn't worried about myself—I only thought of Katherine.

When Dr. Crane performed the ultrasound, Katherine's heart was barely beating. My doctor turned to my husband and said, "I can't deliver this baby. I could try, but I'm convinced we would end up doing a cesarean and under the circumstances, that is just too dangerous." He said, "I have to send you to Dr. McMahon."

I gasped out loud. Dr. Crane said to Jim, "This is about Coreen now." I began to cry. Again I said, "What about a cesarean?" Dr. Crane said, "I can't justify that risk to you. There is a safer way." When I saw the anguish on my doctor's face, I knew that we had no other choice. Dr. Crane supported us so much in our decision to have Katherine naturally, and he knew that we would have to live with our decision for the rest of our lives. When I saw the pain on his face, I knew I had to go. This wasn't a choice anymore. It wasn't up to us. There was no reason to risk leaving my children motherless if there was no hope of saving Katherine.

We drove to Los Angeles. I cried the whole way, patting my tummy and promising Katherine we would never let anyone hurt or devalue her. On the way, Jim was adamant that if we weren't comfortable, we would turn around and leave no matter what. There was no way he would let his little girl's life end in a way that didn't give her respect and dignity. I'd never felt so scared and sick to my stomach in my life. I kept asking God, "Why are you making this so difficult for us?"

We expected a cold gray building . . . we expected an abortion mill. We expected people who cared about me, but not about Katherine. When we arrived, the place was beautiful and peaceful. But when we walked in, I was still very defensive. I didn't trust these people.

The staff greeted us with such warmth and kindness. I was immediately taken in to see Gale McMahon, the clinic's head nurse. We started to talk, and Gale asked if we had named our baby. "Her name is Katherine Grace," I said and began to cry. When I looked up, she too had tears in her eyes. At that moment a little bit of my wall broke down.

Gale explained the procedure in detail. My husband asked a lot of questions. I was numb—I just kept thinking about Katherine. We then went in to see Dr. McMahon. As he met with us, he performed another ultrasound. I can't tell you the compassion he had for us. He knew how much discomfort I was in from the polyhydramnios and the size of my uterus, and how much we were both suffering at losing our little girl. He was so gentle and kind.

Dr. McMahon immediately asked me the same question Gale had: "Have you named her?" He never referred to her as fetal tissue, or a fetus, or even just a baby. She was always Katherine.

He told us that my condition meant that we had to do this procedure right away. My uterus was far too full of fluid to wait. We asked if there was any way that Katherine could be born alive. He looked carefully at the ultrasound, measured her head and explained sadly how large it was, and said that there was no way it could fit through my cervix without draining some of the fluid. He also explained that due to the difficulty of the position she was in, they would have to go inside my womb and for that, I would be put under heavy anesthesia. With her heartbeat as irregular and slow as it was already, he did not think she would survive the anesthesia.

It was so hard to accept, but we began to understand that it was what we had to do. After Dr. McMahon explained the procedure to us again, I felt comforted. He and his staff understood the pain and anguish we were feeling. I realized I was in the right place. This was the safest way for me to deliver. This left open the possibility of more children. It greatly lowered the health risk to me. Most important, it offered a peaceful, painless passing for Katherine Grace.

For many women, this procedure takes longer, but I went into labor very quickly after Dr. McMahon put in the first set of dilators. When I came back the next morning, my cervix was already dilated sufficiently, and it was time to begin the surgery. I was put under anesthesia. When I awoke a few hours later, Katherine was brought in to us. Gale gave her to me and said, "She's beautiful." Gale helped me to bond with her. She really was beautiful. She was not missing part of her brain. She had not been stabbed in the head with scissors. She looked peaceful. My husband and I held her tight and sobbed.

One of the things I noticed when I was holding Katherine was that the socks we bought for her were too big. Someone had taken tiny, soft pink ribbons, and tied them gently at the ankles so that her socks would fit. I can't tell you the peace that brought me. I knew they were taking care of her just as we would. We stayed with her for hours, praying and singing lullabies. Giving her back was the hardest moment of my life.

Dr. McMahon and his staff helped us get through the dark days to come. They counseled us and gave us information on help for dealing with our grief—not just for Jim and me, but for our children, so they could get through the grief of losing their sister, and for our parents, so they could cope with their grief at losing their granddaughter.

When I went back for my checkup, Dr. McMahon was so pleased that I was recovering well physically. But he was worried about how I was doing emotionally, and we talked a lot about how I felt. My arms were physically aching, and he told me I wasn't alone, that so many women feel that way. Your arms ache to hold your baby. And then he told me something I've never forgotten. He said, "People don't want to know that this happens. They don't want to know that there are babies born with their brains outside their skulls, that there are babies for whom life is not a gift but only cruelty and pain and death. They don't want to know what families like yours have to suffer." I didn't realize just how true that was until I came here.

I know how many of you feel about abortion, because that's how I felt. I still am against abortion. Before this happened to me, I had a friend who had something terrible like this happen in a pregnancy she'd wanted very much. I tried to be empathetic and I never said anything to her that was not kind, but in my heart there was a part of me that judged her. I knew that I would never make that decision. I don't judge anymore.

When I lost Katherine, I was devastated. For some reason God chose not to give her the gift of life. But losing her taught me how precious that gift of life is. I have my health, I have the ability to walk, to run, to enjoy life with my husband and my wonderful children. That is the gift that Dr. McMahon's procedure gave me and I am grateful for that every day of my life.

Because of the safety of this procedure, I am now pregnant again and will have another baby in June. Thanks to the grace of God and the skill and compassion of Dr. McMahon, I can have another healthy baby. If you outlaw this surgical procedure, other women like me will be denied that gift, that joy. They may lose their ability to have more children; they may lose their health; they may lose their lives. The child that I carry today is by no means a replacement for Katherine. There will always be a hole in our hearts where she should be, but this baby is a sign that life goes on and that God is good.

Someday, we'll tell our little boy or girl this story. We'll talk about Katherine, and how she changed our lives—and how, in a way, she went to Washington. We'll talk about how, even though her life ended before it could really begin, the way she left this world allowed us to have this new miracle. We pray that this story has a happy ending. We pray to be able to tell Chad, Carlyn and their little brother or sister that when Congress heard, really heard, the truth about the surgery that helped their Mom, the members of Congress realized that they had no business doing what they were trying to do. They knew that they could never understand. We didn't understand before. Now we do. I pray that you will understand as well and put a stop to this terrible bill. When you vote on this bill again, please remember me. Remember my face, remember my name, remember my family and the child I am carrying.

Mr. CANADY. Ms. Line.

STATEMENT OF MARY-DOROTHY LINE, LOS ANGELES, CA

Ms. LINE. My name is Mary-Dorothy Line. I'm here today to oppose H.R. 1833. This legislation would outlaw a compassionate medical procedure that helped me and my family through the most difficult situation in our lives.

I am a registered Republican and a practicing Catholic. My husband Bill is a consulting engineer. We currently live in Los Angeles, CA.

Having children was not a decision we took lightly. We waited until we were financially, emotionally, and spiritually prepared. And last April 1995 when we found out I was pregnant, we were very excited. We waited until Father's Day to tell our families. We thought that would be an extra special Father's Day present.

I studied all the books I could about pregnancy and parenting, and I talked to my doctor and I did everything she told me to do. We debated over having an amniocentesis test, but my doctor told me it wasn't necessary, due to my age—I was under 35—and no history of genetic problems in either of our families. So we decided that we would do an alpha fetal protein test. This is a test that is normally done in most pregnancies. It is a simple blood test.

A week and a half later, the doctor called me with the results of the test, which told me that there was an abnormal test result and that I should have an amniocentesis test. My husband and I talked about it. An abortion was not an option. This was our baby. We were very strong; God would not give us more than we could handle, but we knew we needed to know what we were dealing with. So we went for the amniocentesis test.

During the ultrasound for the amniocentesis test, the doctor noticed that the ventricles to the baby's brain were overly dilated, and he had too much fluid in his head. He told me to have another ultrasound in 2 weeks. I didn't really know what that meant, so I rushed to my Ob/Gyn's office and she explained to me that's called hydrocephalus. If there is too much fluid in the baby's brain or in the baby's head, a brain cannot develop. I told my husband, and he told me not to worry, that everything would be OK in 2 weeks. We really believed everything would be OK.

At this point in time was when we were moving from Chicago to Los Angeles. So we had a week to drive across the country and to talk and think and pray. When we arrived in Los Angeles, there was a letter waiting for us at our new apartment telling us that the amniocentesis results were perfect. Those were the exact words they used: "perfect."

The next day was Sunday. We went to church and we thanked God because our problems were over. When we called our families to tell them that the results were perfect, my mother-in-law said to me, "What about the fluid-in-the-head problem?"

And I said, "Oh, don't worry about that. Everything is going to be fine. We've been praying so hard."

The next day was my husband's first day at work, and we had a visit scheduled with the perinatalogist. We used to live in Los Angeles, so I had a doctor there, an Ob/Gyn, that I was very comfortable with. I had known him for quite some time. And I thought it would be—so he recommended the perinatalogist.

My husband did go with me. I picked him up at work after he had been there only a few short hours. The doctor, Dr. Connie Agnew, asked why we were there. We told her what the doctors in Chicago had told us. She said she would make her own diagnosis, so just sit tight.

Within about a minute, she told us she did not have good news, that it was a very advanced textbook case of hydrocephaly. My husband almost passed out. We asked what we could do, and she said there was absolutely nothing. An hydrocephalic baby far advanced has no hope. I was about 22 weeks pregnant. The doctor would most likely—the baby would most likely be stillborn, and she recommended we terminate the pregnancy.

Our Ob/Gyn in Los Angeles, Dr. William Frumovitz, recommended a second opinion. He sent us to Cedar Sinai Hospital to Dr. Dru Carlson. Dr. Carlson stayed late to see us and confirmed our worst fears. She asked us to bear with her as she looked examined our baby, the baby we knew we would never have. She worked very hard for 45 minutes, and she told us that, in addition to the hydrocephaly, the baby had almost no stomach and that he could not swallow. Obviously, a baby with no brain, stomach, or ability to swallow could not survive. So she also recommended we terminate the pregnancy.

My poor husband had the horrible job of calling our parents and grandparents and telling them the awful news. My father started crying; we were all crying. This couldn't be happening to us, but it did.

All three doctors referred us to Dr. James McMahon. They said that the procedure that he performs, the intact dilation and evacuation, is the best and safest procedure for me to have. The multiple days of dilation would not be traumatic to my cervix, and this was very important to preserve my body for future pregnancies. Dr. Carlson said that with this type of procedure an autopsy could be performed to see if there were other problems that we could try to avoid future pregnancies. That's one reason why this procedure is so important, because people can see and hold and bury their babies, and they can be studied to see if there is other genetic problems.

After the dilation—the dilation took 3 days—I'll speed up; I'm sorry—and two trips a day to his office.

Mr. WATT. Mr. Chairman, I'll be happy to yield my 5 minutes to this lady.

Ms. LINE. Thank you very much, sir.

These were the worst days of our lives. We lost our baby before we even had him.

After the dilation was complete, I was put under heavy anesthesia, and a simple needle was used to remove the fluid from our son's head. This is the same fluid that killed him. This enabled his head to fit through my cervix. No scissors were used, and no one sucked out my baby's brains. A simple needle was used.

My husband and I were so disturbed by the way this compassionate medical procedure has been portrayed. We are very private, personal people, but I am here today because of this, because we were so disturbed.

We thoroughly investigated this procedure before we had it. Every specialist we saw told us it was safe and very compassionate. What they're saying—and, like I said, what you guys have been saying is just so disturbing, that I went back to Dr. McMahon's office to try to figure out why this procedure was being portrayed the way it was, totally misrepresented.

We are the truth squad that was mentioned earlier today, Coreen and I. This was not birth control. We desperately wanted our babies. This was the hardest thing I have ever been through, and I pray it's never going to happen to anyone again, but it will. It's probably happening to someone right now, and those of us unfortunate enough to have to live through this need a procedure which will give us hope for the future.

I am very lucky that I was able to have this procedure. Because the trauma to my body was minimized, I was able to become pregnant again only 4 months later. We are expecting another baby in September. Dr. McMahon and the intact dilation and evacuation procedure made this possible for us.

One of the first things Dr. McMahon told us was that his job was not done until he and his staff receive a baby picture of our next child. At that time I couldn't ever imagine becoming pregnant, but a month later it was all I thought about. I desperately wanted to be pregnant and to finally start our family. This procedure gave us hope. Please don't take that away from the families who will need it after us. You must leave medical decisions to the families and the medical experts who have to live with the consequences. This is not the place of government to interfere in these very private, personal decisions.

Thank you.

[The prepared statement of Ms. Line follows:]

PREPARED STATEMENT OF MARY-DOROTHY LINE, LOS ANGELES, CA

My name is Mary-Dorothy Line. I am here today to oppose H.R. 1833. This legislation would outlaw a compassionate medical procedure that helped me and my family through the most difficult situation in our lives. I have come to Washington to oppose this legislation to ensure that it is available to other women and families in the future.

I am a registered Republican and a practicing Catholic. My husband, Bill, is a consulting engineer. We live in Los Angeles, California. Bill and I got married while in college. We had been married almost 14 years before we decided to start our family. Since having children was not a decision we took lightly, we waited until we were financially, emotionally, and spiritually prepared. In April of 1995 when we found out I was pregnant, we were thrilled. We waited to tell my father and our other family members until Father's Day—an extra special Father's Day present.

The first four months proceeded normally. Dr. Pamela Lui, an OB/GYN at Northwestern University Hospital in Chicago was my doctor and I followed her instructions exactly. I read everything I could about pregnancy and parenting. We debated having an amniocentesis, but Dr. Lui said that it was not necessary due to my age (under 35) and no family history of genetic disorders. But she did recommend an alpha-fetoprotein (AFP) test which is routinely performed in most pregnancies to screen for neurological anomalies such as spina bifida. The nurse who drew my blood for the AFP said she would call me with the results in about two weeks, but if there was a problem, the doctor would call.

When Dr. Lui called I was not thinking and started chatting away to her until I remembered what the nurse said; my heart started pounding. Dr. Lui told me that the AFP showed an elevated level of something which might indicate that there was a problem with our baby. She advised us to have an amniocentesis even though the chances were still great that everything was fine.

My husband and I talked about what we would do if there was something "abnormal." We quickly decided that we are strong people and very much in love and, that while having a mentally or physically disabled child would be hard, that it would not be too hard. But we also decided that we needed to know what we were dealing with, so I made an appointment with a perinatalogist at Northwestern Hospital to have an amniocentesis. During the ultrasound for the amniocentesis, the doctor noticed that the baby's head was too large and that there was a lot of fluid in his head. He told me to have another ultrasound in two weeks to check the progression.

I had no idea what all this meant so I rushed to Dr. Lui's office and asked her to explain. She drew some pictures and explained that the condition was called hydrocephalus; that in every person's head there is fluid to protect and cushion the brain, but if there is too much fluid, the brain cannot develop. I called my husband at work and had him taken out of a meeting to ask him to meet me right away. I explained everything to him. He said that everything would work out and not to worry. We actually believed everything would be OK in two weeks.

I told my father that we might have a problem, but he also said that everything would be fine since there are no genetic problems in either Bill's family or mine. When we told my mother-in-law, she said she would pray for us. We are all Catholic and go to church every week. When we have problems and worries, we turn to prayer. So, we prayed, as did our parents and grandparents.

To complicate matters even more, while these problems were occurring Bill and I were in the process of moving from Chicago to Los Angeles for my husband's job. As we were driving across the country, we had a week to talk and think and pray.

We arrived at our new apartment in Los Angeles on Sunday afternoon to a letter from Northwestern Hospital in Chicago saying that the amniocentesis results were perfect. We were so relieved. I knew that there was still a chance that the excess fluid on the brain was a problem, but we had been praying so hard and wanted this baby so much that we truly believed that everything was going to be fine. Since it was Sunday, we went to church and thanked God. We went to bed happy that night; our worries were over.

Monday was my husband's first day of work at his new job. I had an appointment scheduled with a perinatalogist from Santa Monica Hospital and Cedar Sinai Hospital for another ultrasound. Bill insisted on coming to the ultrasound, even though I told him that he did not need to be there—after all, it was his first day of work. But I did think it would be exciting for him to see our baby on the ultrasound. I was 21 weeks pregnant.

The doctor, Dr. Connie Agnew, asked why we were there. We explained what the doctors in Chicago had told us and she said she would make her own diagnosis. After about a minute, she told us that she did not have good news; it was a very advanced textbook case of hydrocephaly. My husband almost passed out. We asked what we could do and she said there was nothing we could do. A hydrocephalic baby that advanced has no hope. The baby would most likely be stillborn. She recommended that we terminate the pregnancy.

Our ob/gyn in Los Angeles, Dr. William Frumovitz, recommended a second opinion. Dr. Frumovitz sent us to a wonderful, compassionate doctor at Cedar Sinai Hospital, Dr. Dru Carlson. She stayed late to see us and confirmed our worst fears. She asked us to bear with her as she looked at our baby to see if there were any other problems besides the hydrocephaly. We sat there and watched as she examined our baby, the baby we knew we would never have. She worked very hard for 45 minutes and then told us that in addition to the brain fluid problem, the baby's stomach had not developed and he could not swallow. We asked about in-utero operations and drains to remove the fluid, but Dr. Carlson said there was absolutely nothing we could do. The hydrocephaly was too advanced. Our precious little baby was destined to be taken from us. Dr. Carlson also recommended that we terminate the pregnancy.

My poor husband called our parents and grandparents and told them the awful news. My father started crying; we were all crying. This couldn't be happening to us. But it did happen to us. Doctors Frumovitz, Agnew and Carlson referred us to Dr. James McMahon. They all said that the procedure that he performs, the intact dilation and evacuation (Intact D&E), was the best and safest procedure for me to have. The multiple days of dilation would not be traumatic to my cervix. This was important to preserve my body and protect my future fertility. They knew that that was very important to my husband and I since we really wanted to have children in the future. Dr. Carlson said that with this procedure they would be able to perform an autopsy to determine if we were likely to face similar problems in future pregnancies. With no hope for this baby, our doctors were recommending the best option, with hope for the future.

Dr. McMahon and his staff were the kindest people you could ever meet. They explained the intact D&E procedure to us. Dr. McMahon used ultrasound to examine the baby, in case the three other specialists were wrong. They were not.

The dilation took three days and two trips a day to his office. These were the worst days of our lives. We had lost our son before we even had him. After the dilation was complete, I was put under heavy anesthesia. A simple needle was used to remove the fluid from the baby's head, the same fluid that killed our son. This enabled his head to fit through my cervix.

My husband and I are disturbed by the way this compassionate medical procedure has been portrayed by members of Congress. We throughly investigated this procedure before we had it. Every specialist told us that it is a safe and compassionate procedure. We were very informed and educated before making this decision. What they were saying in Congress bothered us so much that I went back to Dr. McMahon's office to try to figure out why this procedure was being misrepresented. Our anger at how this procedure was portrayed is why I am here today.

This is the hardest thing I have ever been through. I pray that this will never happen to anyone ever again, but it will and those of us unfortunate enough to have to live through this nightmare need a procedure which will give us hope for the future. With this procedure families can see, hold and even bury their babies. In addition, the baby can be visually or clinically studied by specialists to determine if there are genetic abnormalities that can be avoided in future pregnancies. I am lucky that I was able to have this procedure. Because the trauma to my body was minimized by this procedure, I was able to become pregnant again, only four months later. We are expecting another baby in September. Dr. McMahon and the intact D&E procedure made this possible for us.

One of the first things Dr. McMahon told us was that his job was not done until he and his staff receive a baby picture of our next child. At the time, I couldn't imagine becoming pregnant ever again. A month later, it was all I thought about. I desperately wanted to be pregnant and finally start our family. This procedure gave us hope. Please don't take that way from the families who will need it after us. You must leave medical decisions to the families and the medical experts who have to live with the consequences. It is not the place of government to interfere in these very private, personal decisions.

Mr. CANADY. Ms. Alvaré.

STATEMENT OF HELEN M. ALVARÉ, ESQ., ON BEHALF OF THE NATIONAL CONFERENCE OF CATHOLIC BISHOPS

Ms. ALVARÉ. Good afternoon. My name is Helen Alvaré from the National Conference of Catholic Bishops, and I thank you for the opportunity to testify. I have been asked to help the subcommittee consider the testimony you've heard today from within a moral framework.

The most important testimony you've heard about partial-birth abortion, of course, is the accurate medical description of what happens in that procedure. In sum, it's designed such that an abortionist kills a human infant who is partially delivered outside of his or her mother's womb. The infant is not directly anesthetized to prevent pain, and, certainly, as you've heard this morning, is not anesthetized to the point of death in the womb prior to delivery. Once so delivered, according to the writings of Dr. Haskell, the infant is killed by inserting a pair of scissors into the base of the skull. And then, as Dr. Haskell also writes, the scissors are spread wide enough to allow the introduction of a catheter to suck out the contents of the skull.

One of the clearest and most compelling guides to the morality of any act is its physical structure. A description of the partial-birth abortion speaks loudly of its own immorality. It is nothing other than the direct killing of an innocent human being, an act deemed immoral and unacceptable through time and across continents. Furthermore, a number of factors make it particularly frightening that this kind of killing could legally continue, let alone derive any support in the United States today.

First, partial-birth kills the most defenseless among us. By virtue of their youth, their physical weakness, their legal powerlessness, and in some cases their physical disability, the victims of partial-birth deserve our most strenuous protection, not the most heinous abortion procedure the industry has invented, particularly in a country that claims to pride itself on its human rights tradition.

Second, the partial-birth abortion bears a far greater resemblance to infanticide than to abortion. It's the slippery slope that many have warned of for years. The pro-life community warned that it wasn't long before the same arguments used to justify the killing of the unborn would be used to justify the killing of the born. We're there already in the sense that we have laws like the ninth circuit coming down justifying the killing of the elderly based on *Roe* v. *Wade*. And here with partial-birth we have attempt at justification of killing the mostly-born. Opponents of the bill keep asking whether enacting it would be the first step to banning all abortions, but the real question is allowing this procedure; won't it be a step toward legalized infanticide?

A fourth reason partial-birth abortion is particularly heinous is because of its pure physical brutality. Forcibly dragging the infant's body out of the womb, stabbing the head, suctioning it—the very violence of each of these is an assault upon the humanity of the victim and upon every doctor or nurse who performs or witnesses.

Turning now to the attempts by advocates of partial-birth abortion to overcome the immorality of the act with the anecdotal examples of witnesses who have testified before me, the testimony we've heard today from mothers who have undergone partial-birth abortions has been quite emotional. It rightly elicits from us emotional sympathy for the extremely difficult situations for women struck by tragedy late in a pregnancy. As a woman myself in the middle of her fifth pregnancy, having lost three, how can I not feel the emotion that I'm hearing today? But it would wrong for me, or for anyone, to conclude that such situations could justify a particularly brutal kind of killing of the innocent.

For the act of deliberately killing a vulnerable human being is wrong, no matter how much the baby had been wanted, no matter how sad the mother is about requesting the procedure, no matter how much she feels that she would never have desired an abortion before this tragedy struck her, no matter how strongly that she feels that it is better for her son or daughter to die in this way than, for example, to die naturally in her arms with pain relief. The moral culpability or lack of culpability of the one who requests the partial-birth abortion cannot transform the killing itself, to right the wrong.

And H.R. 1833 is only about judging the act itself, not the mother who requests it. It is most definitely not about judging Ms. Costello's or Ms. Line's, or any other woman's, personal culpability. It is the proper place of law in society—I have about 30 seconds more—to reflect our collective judgments about what is objectively wrong. And partial-birth abortion, no matter the motivations that lead to them, are objectively cruel to the victims. Even prescinding from the fact that Dr. Haskell and others who perform this do not claim that in most cases they're addressing the mother's physical health or her life, or even a health problem with the baby, we cannot make this act, this wrong act, right by asserting that the victim was disabled, something that has been repeated today.

It is not enough that the disabled struggle every day in our country with prejudices, large and small. Can Congress really be in the position of telling them that partial-birth abortions are going to be allowed to continue on the strength of testimony that they make it easier for parents to say goodbye to their disabled children, because they can do so in one piece as opposed to, for example, the dismemberment that would occur with an alternative procedure? Although we all wish to relieve as much pain as we can from a parent's suffering at the prospect of a disabled or imminently dying child, we can't say this to the disabled.

And I want to thank you again for the opportunity to present this testimony today.

[The prepared statement of Ms. Alvaré follows:]

PREPARED STATEMENT OF HELEN M. ALVARÉ, ESQ., ON BEHALF OF THE NATIONAL CONFERENCE OF CATHOLIC BISHOPS

Good morning and thank you for this opportunity to testify. I have been asked to help you consider the testimony you have heard today from within a moral framework.

The most important testimony concerning partial birth abortion that has been presented to you today concerns the accurate medical description of what happens during this procedure In sum, this procedure is designed such that an abortionist kills a human infant who is partially delivered outside of his or her mother's womb. The infant is not directly anesthetized to prevent pain. Certainly, the infant is not anesthetized to the point of death in the womb prior to his or her partial delivery outside of the mother's body. Once so delivered, according to the writings of one prominent practitioner of this method, Dr. Martin Haskell, the infant is killed by inserting a pair of sharp curved scissors into the base of the child's skill. The scissors are then spread wide enough to insert a catheter to suction out the contents of the skull before the head is collapsed and the infant fully delivered outside of the mother.

One of the clearest and most compelling guides to the morality of any act is the physical structure of the act itself. The above description of the partial birth abortion speaks loudly of its own immorality. The partial birth procedure is nothing other than the direct killing of an innocent human being, an act deemed immoral and socially unacceptable through time and across continents. Furthermore, a number of factors make it particularly frightening that this kind of killing could legally continue—let alone be knowingly tolerated or even supported by some—in a society that hopes to have any pretensions about human rights.

First, the partial birth abortion kills the most defenseless among us. By virtue of their youth, their physical weakness, their legal powerlessness, and in some cases, their physical disability, the victims of partial birth abortion deserve our most strenuous protection, not one of the most gruesome forms of death the abortion industry has to offer. Particularly in a country that prides itself on offering opportunity for the weakest among us, the partial birth abortion is a violation of everything we stand for.

Second, the partial birth abortion bears a far greater resemblance to infanticide than It does even to abortion No reasonable person can disagree, once he or she has read a description or seen an accurate drawing of the partial-birth abortion method. it is one-fifth abortion and four fifths infanticide. It kills a child when 80% of his or her body is already outside the womb. And there should certainly be a moral and legal consensus in our country that infanticide is a crime and that it cannot be tolerated in a civilized society.

This, the partial-birth abortion, is the slippery slope many have warmed of for years. It was abortion advocates who established the moment of "birth," the moment the child begins to exit the mother's womb, as the dividing line between legal and illegal destruction of human life In fact, when abortion advocates attacked every other provision of the Texas abortion law in *Roe* v. *Wade,* the one provision they did not attack was a criminal ban on the killing of a child who had begun to leave the womb. *Roe* v. *Wade,* 410 U.S. 113, 117 n. 1 (1973). In fact, that law remains on the books in Texas today.

But the pro-life community warned that it would not be long before the same arguments used to justify killing the unborn would be used to justify killing born humans. And for a time, the Supreme Court itself slid a considerable distance down that slope, invalidating even laws requiring a physician to care for children who have survived an abortion attempt. Noting this trend, one commentator said that the Court had begun to treat the event of birth "as somewhat like a state border, which an officer of one jurisdiction may disregard if he is following a fugitive in hot pursuit." (James Burtchaell, "How Much is A Child Worth?: From Abortion to Infanticide," in *Rachel Weeping and Other Essays on Abortion* (Kansas City: Andrews and McMeel 1982) p. 288). Such extremism has since been tempered by the Court in *Webster* and *Casey*—but its spirit lives on among the leaders of the legal abortion movement and members of the abortion industry

If partial-birth abortions remain legal, if this Congress allows them to continue, what could be next on this slippery slope? Killing children who have emerged from the womb 3 or 4 inches more? That is, children completely bum, but still attached by an umbilical cord? Killing them a few minutes after complete birth? Or maybe a few hours later, when a doctor has had the opportunity to determine if the child suffers any disabilities? All of these have already been suggested by scholarly writers who support late-term abortions.[1]

Opponents of this bill keep asking whether enacting it would just be the first step in an effort to ban all abortions. But the real question should be whether allowing this procedure would serve as a step toward legalized infanticide?

Third, allowing the continued practice partial birth abortions will harm the common good. Legally unchecked, the practice of partial birth abortion is spreading. Practitioners like Dr. James McMahon acknowledged that he was teaching other doctors to perform partial-birth abortions. The National Abortion Federation noted in the *New York Times* that more doctors are recently reporting using this method. One doctor quoted said that not only has he done it and taught it for the last 10 years, but he knows doctors in other cities that do the same (Tamar Lewin, "Wider impact is Foreseen for Bill to Ban Type of Abortion," *The New York Times*, Nov. 6, 1995, p. A10).

There is an old axiom that those who harm fellow human beings end up doing more harm to themselves: "The handle is more dangerous than the sword." By shutting themselves off from others' humanity, they end up dehumanizing themselves. If doctors are allowed or even encouraged to perform partial-birth abortions—if Americans, now exposed to them through this very legislative debate, are told that they must accept them as legal—one of the ultimate consequences will be a further denigration of the value of human life. The common good will suffer.

A fourth reason the partial birth procedure is a particularly heinous procedure is due to its pure physical brutality. Forcibly dragging the greater part of the infant's body out of the womb with forceps. Stabbing the head. Suctioning it. The very violence of each of these is an assault upon the humanity of the victim, as well as upon the humanity of every doctor and nurse who performs or witnesses it.

Fifth and finally, the partial birth procedure is worthy of special condemnation because of the cynicism of its inventors in calculating how to skirt the law against homicide. Knowing that if an intact child were fully delivered and then killed, homicide statutes could be applied, abortionists like Dr. Haskell calculated how to leave some part of the child inside his or her mother to attempt to gain the protection of *Roe* v. *Wade*. Such cynical manipulation of the law ought not to be allowed.

Turning to the attempts by advocates of partial birth abortion to overcome the immorality of the act with anecdotal examples. The testimony we have heard today from mothers who have undergone partial-birth abortions has been quite emotional. It rightly elicits from us emotional sympathy for the extremely difficult situations faced by women struck by tragedy late in a pregnancy. It would be wrong, however, to conclude that such a situation could justify a particularly brutal kind of killing of the innocent.

One preliminary point here. It is important to remember that personal testimony about an abortion procedure is relevant to the bill at issue today only if it involves a child who was alive at the time it was partially delivered outside of the mother and then killed. To the extent that it is true that Ms. Costello's baby died in the womb from anesthesia or any other cause, of course, her testimony bears no relevance to the procedure at issue today.

To the extent that Ms. Costello may have been misled, and actually did undergo the procedure to be banned by H.R. 1833, still, her testimony could never change the need for the passage of H.R. 1833. For the act of deliberately killing a vulnerable infant is wrong no matter how sad the mother is about requesting the procedure, no matter how strongly she feels that it is better for a human being to die this way than, for example, to die naturally in the arms of his or her family. The moral culpability or lack of culpability of the one who requests the partial birth abortion cannot transform the killing itself from wrong to right.

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[1] *See, e.g.*, Michael Tooley, "Abortion and Infanticide," *Philosophy and Public Affairs* 1, no. 2 (Fall 1972): 37–65; Joseph Fletcher, "Indicators of Humanhood: A Tentative Profile of Man," *Hastings Center Report* 2, no. 5 (Nov. 1972): 1–4.

And H.R. 1833 is only about judging the act itself, not the person. It is most definitely not about judging Ms. Costello's or any other woman's culpability. It is the proper place of law in society to reflect our collective judgments about what is objectively wrong. And partial birth abortions, no matter the motivations which lead to them, are objectively cruel to the victims, objectively wrong.

We cannot, in particular, make this wrong act right by asserting that the victim was disabled. Is it not enough that the disabled struggle every day in our country with prejudices large and small? Could Congress ever be in the position of telling them that partial birth abortions would be allowed to continue on the strength of testimony that they are particularly necessary to make it easier for the parents of disabled children to say "goodbye" to their children because they leave the infant body in one piece instead of the many pieces produced by alternative kinds of abortions? Although we all wish to relieve as much pain as we can for a parent suffering at the prospect of a disabled or imminently dying child, we can never say this.

Thank you again for this opportunity to present testimony today and to clarify the moral questions raised by the partial birth abortion procedure.

Mr. CANADY. Thank you. We thank all the members of this panel for your testimony.

I have a question for Ms. Shafer. Dr. Haskell has said that you never witnessed him perform a partial-birth abortion. In fact, the claim was made in the full Judiciary Committee during the full committee markup, from a letter by Dr. Haskell, that your eyewitness account was false. Would you like to respond to those allegations that were made against you here in the Judiciary Committee?

Ms. SHAFER. Yes, I would. Last July 12, I sat here as this committee debated the legislation, and I heard Congressman Schroeder read a letter from Dr. Haskell to the Judiciary Committee, also dated July 12, in which he said, and I quote, "I have examined our records and found no evidence of Brenda Shafer working for us during 1993."

Fortunately, I had previously provided the Judiciary Committee's Constitution Subcommittee with the pertinent payroll records from Kimberly Quality Care, including their invoice to Dr. Haskell's clinic. After these documents were circulated, Congresswoman Schroeder withdrew the particular allegation, explaining it away as resulting from confusion by my married name. But it seemed peculiar to me at the time that neither she nor her staff had contacted me, or the subcommittee staff, to request documentation before she basically called me a liar in front of everybody.

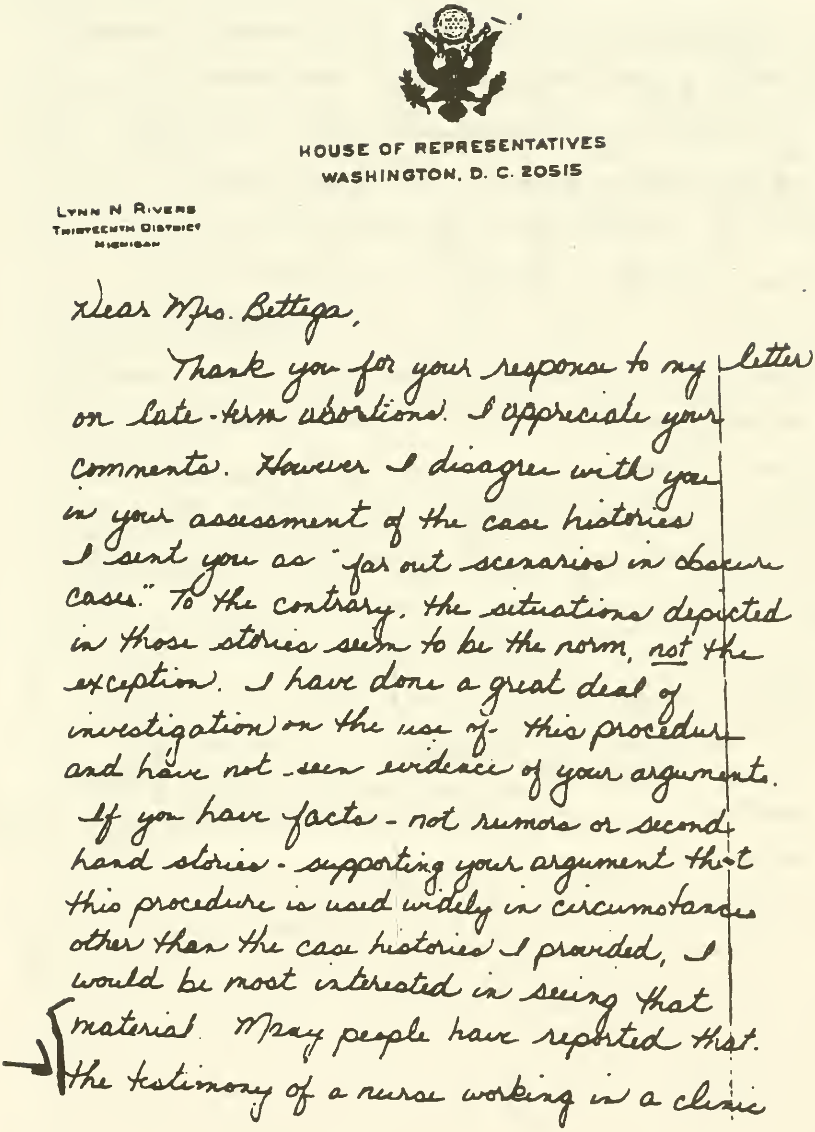
But there was more of that sort of thing to come. In his July 12 letter, Dr. Haskell also said that my account was "inaccurate," because "she describes procedures at 26½ weeks and 25 weeks. This is contrary to my own self-imposed and established limit of 24 weeks."

But in recent times I've seen an article published in American Medical News, July 5, 1993, just a few months before I worked for him, in which Dr. Haskell said that he performs the procedure up to 25 weeks, which conflicts with his letter to the Judiciary Committee.

Also, in Dr. Haskell's 1992 paper describing the partial-birth procedure, dilation and extraction for the late second-trimester abortion, which you have all seen, he wrote, "This author routinely performs this procedure on all patients 20 through 24 weeks LMP [last menstrual period] with certain exceptions. The author performs the procedure on selected patients 25 through 26 weeks LMP [last menstrual period].” Keep in mind that the 26½-week little boy had Down syndrome, and that was a “special case.”

Mr. Canady. You have provided the subcommittee with a copy of a letter written by one of our colleagues here in Congress, Congresswoman Lynn Rivers, to one of her constituents. In that letter, Ms. Rivers writes of you, “The nurse was repudiated by the doctor of the clinic because she had worked at the facility for only three days and had not assisted surgically. So she was never in a position to observe the actual procedure. Even more importantly, this nurse was unwilling to testify under oath or submit herself to cross examination in front of Congress, even though she was sitting in the hearing room while testimony was being taken. Unfortunately, her comments are being repeated as fact.”

[The information follows:]



HOUSE OF REPRESENTATIVES
WASHINGTON, D. C. 20515

LYNN N. RIVERS
THIRTEENTH DISTRICT
MICHIGAN

Dear Mrs. Bettega,

Thank you for your response to my letter on late-term abortions. I appreciate your comments. However I disagree with you in your assessment of the case histories I sent you as "far out scenarios in obscure cases." To the contrary, the situations depicted in those stories seem to be the norm, not the exception. I have done a great deal of investigation on the use of this procedure and have not seen evidence of your arguments. If you have facts - not rumors or second-hand stories - supporting your argument that this procedure is used widely in circumstances other than the case histories I provided, I would be most interested in seeing that material. Many people have reported that the testimony of a nurse working in a clinic performing late term abortions provides ample proof of your argument but the nurse in question was repudiated by the director of the clinic because she had worked at the facility for only 3 days and had not assisted surgically so was never in a position to observe the actual procedure. Even more importantly, this nurse was unwilling to testify under oath or submit herself to cross-examination in front of Congress - even though she was sitting in the hearing room while testimony was being taken. Unfortunatly her comments are being repeated as fact."

I am sorry that we disagree on this issue but no matter which side I take, someone will be "grievously disappointed" in my voting record. Rather than fight on this highly divisive question, I would hope we can work together to eliminate the demand for choice.

Lynn

Mr. CANADY. Were you ever unwilling to testify before Congress about what you saw at Dr. Haskell's clinic?

Ms. SHAFER. No, sir, I have always come forth when I've been asked. On the subcommittee of the Congress, I came in after that committee, but I did sit here in the markup. Then I was asked to testify before the Senate, which I did very readily. Then I was asked to testify today, which I came here also. And every time I've ever been asked to do anything, I've done it. But I find it awfully funny that Dr. Haskell was asked to testify at that first hearing, which he declined. He was also asked to testify at the Senate committee, which he declined. He was also asked to come here today, and I don't think I see him anywhere.

Mr. CANADY. OK. Thank you very much. I don't have any more questions at this point.

Mr. Watt, I believe you had about 3 minutes remaining on your time.

Mr. WATT. Mr. Chairman, I doubt that I will take three minutes, but I do want to express my thanks to all of these witnesses for being here today.

I, when I was in the State legislature for a very short period of time, was often asked my position on abortion, and since I've been an elected official at this level, I've been asked my position on abortion. And I think these witnesses, all of them, confirm in my own mind the position that I have always taken, which is that my position on abortion is really irrelevant. The people who have to really wrestle with this every day are the people who are confronted with it. And seeing the whole range of emotions and positions reaffirms my belief that this can only be an individual personal decision of the mother and the family, in consultation with whomever they wish to bring into that consultation. And I thank all four members of this panel for helping me to reaffirm that today.

I yield back the balance of my time.

Mr. CANADY. Thank you, Mr. Watt.

Mr. Hyde.

Mr. HYDE. Thank you very much.

I totally respect the views of my friend from North Carolina, and I have nothing but admiration and esteem for every member of the panel that we've just heard. I have a different view, and I don't insist I'm right and you're wrong; I just have a different view.

I think being elected to Congress, I think being a human being, a member of the human family, we all have a duty to protect the innocent, vulnerable, and defenseless. We are our brother's keeper. And I think an unborn child is a member of the human family, and I think that unborn child, no matter how tiny, no matter how defective by our standards, is entitled to life, liberty, and the pursuit of happiness. And when a mother—and it's so easy for me to say; I know that, but when she decides that, for whatever reason, that her unborn child must be disposed of, then who's going to protect that child? Is that child worth protecting? How much value do we assign to that child? It's not a person, said the Supreme Court arbitrarily.

I feel differently. I feel that we're all brothers and sisters; every child is made in the image and likeness of God; no matter how defective or how handicapped, it's a call for our love.

And I'd like to use the rest of my time just reading a letter that was received by Mr. Canady from a lady in Oak Park, IL. I used to represent Oak Park. And I'd like you to listen to this.

> Dear Congressman Canady:
>
> In June of 1993 I was 5 months along carrying twins. My husband and I were notified that one of the twins, our daughter Mary, suffered from a severe neural tube defect. Mary's prognosis for life was slim, and her chance at normal development nonexistent. Her severe abnormality complicated the twin pregnancy and specialists encouraged amniocentesis and Mary's abortion.
>
> Though severely disabled, we knew that Mary was a member of our family and was entitled to live out her allotted time without being assaulted by instruments or chemicals. When it became clear that Mary, whose brain had developed outside of her skull (an occipital encephalocele) would not survive normal labor, we opted for a cesarean delivery.
>
> Born December 13, 1993, a minute after her healthy big brother Will, Mary lived 6 hours cradled peacefully in her father's arms. She was with us long enough to greet her grandparents and our close friends. She also gave a special gift to other children: the gift of life. On the day of her funeral we received a letter from the Regional Organ Bank of Illinois. Our daughter's heart valves were a match for two Chicago infants, critically ill at the time of Mary's birth. We have learned that even encephalic babies and meningomyelocele children like our Mary can give life, or sight, or strength to others.
>
> The death of a child is the most tragic experience many of us will ever face. As parents, we can do only what we can—insure that our children do not suffer. As we now know, when their natural time comes, it can be comforting that their short life has become a gift to others.
>
> Our daughter, living less than a day, saved the lives of two other children. Which of us, even after decades of living, can make the same claim?
>
> Sincerely, Jeannie Wallace French.

Thank you, Mr. Chairman. I ask that this be made a part of the record.

Mr. CANADY. Without objection.

[The information follows:]

J.W. French
738 S. East Ave.
Oak Park, IL 60304
708-848-9165

Charles T. Canady
Chairman, Committee on the Constitution
1222 Longworth
Washington, DC 20515

October 30, 1995

Dear Congressman Canady,

Opponents of HR 1833, "The Partial-Birth Abortion Ban Act," claim that partial-birth abortion is justifiable when performed on babies with disabilities. Please consider the personal experience of our family as you debate HR 1833 on the floor of the House.

In June of 1993 I was 5 months along carrying twins. My husband and I were notified that one of the twins, our daughter Mary, suffered from a severe neural tube defect. Mary's prognosis for life was slim, and her chance at normal development nonexistent. Her severe abnormality complicated the twin pregnancy and specialists encouraged amniocentesis and Mary's abortion.

Though severely disabled, we knew that Mary was a member of our family and was entitled to live out her allotted time without being assaulted by instruments or chemicals. When it became clear that Mary, whose brain had developed outside of her skull (an occipital encephalocele) would not survive normal labor, we opted for a Cesarean delivery.

Born December 13, 1993, a minute after her healthy big brother Will, Mary lived 6 hours cradled peacefully in her father's arms. She was with us long enough to greet her grandparents and our close friends. She also gave a special gift to other children: The gift of life. On the day of her funeral we received a letter from the Regional Organ Bank of Illinois. Our daughter's heart valves were a match for 2 Chicago infants, critically ill at the time of Mary's birth. We have learned that even anencephalic babies and meningomyelocele children like our Mary can give life, or sight, or strength to others.

The death of a child is the most tragic experience many of us will ever face. As parents, we can do only what we can — insure that our children do not suffer. As we now know, when their natural time comes it can be comforting that their short life has become a gift to others.

Our daughter, living less than a day, saved the lives of two other children. Which of us, even after decades of living, can make the same claim?

Sincerely,

Jeannie W. French

Jeannie Wallace French

Ms. COSTELLO. May I respond to that, if possible?

Mr. CANADY. Well, we're going to—I'd yield now to Mr. Conyers.

Ms. COSTELLO. There's—OK, I'm sorry.

Mr. CONYERS. Well, Mr. Chairman, we've been here all day with the witnesses, and I don't see what a few seconds or maybe an extra minute given to Ms. Costello would do to harm the proceedings.

Mr. CANADY. OK, we'd be happy for you yield to Ms. Costello.

Mr. CONYERS. You don't have to help me yield to her. I'm going to do that. I was thinking that you might be the one to do it.

Ms. COSTELLO. And I would greatly appreciate it——

Mr. CONYERS. I would be happy to yield to the lady.

Ms. COSTELLO. Thank you very much.

Mr. CONYERS. You're more than welcome.

Ms. COSTELLO. I would like to respond to Representative Hyde. I was able to testify next to Ms. French in the Senate Judiciary hearings, and I found her story beautiful and compelling. There was a major difference between her story and ours, and that she was carrying twins. They were able to do a cesarean section due to the life of Paul, her other son, who was—life was in jeopardy at any other procedure. So being able to do a cesarian on it because there was a live baby in her womb—that was not an option for us. Doctors have an ethical problem with doing a cesarian on a baby who is not going to survive and putting the woman's life at risk. That is what the experts at Cedar Sinai told me; that is what the board at Cedar Sinai told me. There was a very big concern about risking major surgery to me for my daughter to die the minute the umbilical cord was cut.

I agree with you wholeheartedly about the life of the unborn. That is why I have respected you for many years. I don't want to be put in a category that somehow we did not respect our children or that somehow we were looking for an easy way out; we were not.

Mr. HYDE. Would the gentleman yield?

Mr. CONYERS. I'd be happy to yield to you, Mr. Chairman.

Mr. HYDE. I thank you for your courtesy. Would you, just for a second?

Mr. CONYERS. Of course.

Mr. HYDE. Your condition was life-threatening, was it not?

Ms. COSTELLO. There—that is a big discrepancy, whether it was life-threatening or health-threatening, and this is the big problem that you guys are all facing. Can they prove my life was in danger? Or they can prove my health was in danger? This is the big dilemma.

Mr. HYDE. Did you believe your life was in danger?

Mr. CONYERS. Wait a minute. Mr. Chairman, could we yield the chairman of the committee some additional——

Mr. HYDE. Oh, I'm sorry. We'll talk later.

Ms. COSTELLO. In order——

Mr. HYDE. I'm sorry, I didn't mean to transgress on your time.

Mr. CANADY. We'll have a second round, if you want.

Mr. CONYERS. Oh, fine.

Well——

Ms. COSTELLO. Thank you, Mr. Conyers.

Mr. CONYERS. First of all, I appreciate the opportunity for all of you to come forward. We have an attorney here on the panel, and I'm just trying to review some fundamental constitutional law.

As I understand it, the Supreme Court establishes the interpretation of the Constitution, and that being the case makes it very difficult for anybody, any court or any laws under the State, to make decisions different from the Supreme Court's interpretation.

Ms. ALVARÉ. Could I respond?

Mr. CONYERS. Yes, you can in a little while.

Ms. ALVARÉ. OK.

Mr. CONYERS. The problem that we have is there is a constitutional question in *Roe* v. *Wade*, and that makes it hard for the Congress to get in between it. That's why we've had these fights over who goes to the Supreme Court. The Supreme Court can reverse itself, but it's very hard for the Congress to change the Supreme Court's constitutional interpretation. Now that creates a pretty big problem.

So any suggestion by you, or any Congressman or Congressperson, for that matter, that we should try to change this interpretation is very difficult because——

Ms. ALVARÉ. If I could——

Mr. CONYERS. Yes, sir?

Mr. CANADY. The gentleman's time has expired.

Mr. CONYERS. Well, I realize it expired, sir. I yielded to the chairman of the committee——

Mr. CANADY. Sure.

Mr. CONYERS [continuing]. And to a witness.

Mr. HYDE. I ask unanimous consent the gentleman have 3 additional minutes.

Mr. CANADY. Without objection.

Mr. HYDE. Thank you.

Mr. CONYERS. Well, that's very generous, Mr. Chairman. I appreciate that.

So think of our dilemma. The problem is that this case or that this legislation is probably, as has been posited many times, if it were to become law, would probably be unconstitutional. Now this puts a problem on the President, since we can pass all the unconstitutional laws we want, and he has pointed out already that there are several infirmities in this law.

To put it simply, there is no life-and-health exception in this legislation. Now it would seem to me that those who really wanted this law could have availed themselves of the opportunity to make such an exception, which would at least take away the constitutional infirmity.

Ms. ALVARÉ. Could I respond to the constitutional question?

Mr. CONYERS. The second problem—I want you to answer all of these.

Ms. ALVARÉ. OK.

Mr. CONYERS. And we've got all day. You're not going anywhere.

Ms. ALVARÉ. No, not anymore. [Laughter.]

Mr. CONYERS. OK, all right.

The second problem is the undue burden on previability abortions as opposed to postviability abortions, a serious problem.

Finally, the language that was used in the bill, containing very little medical terminology, is probably in trouble because of vagueness. The President has already announced that.

So I was hoping that this hearing would be a hearing in which these problems, already flagged, would be corrected, but, alas, I am wrong. I invite your response. I'm sure the chairman will give you enough time to respond.

Ms. ALVARÉ. Thank you.

The prior hearing did consider some of these constitutional questions, but I will mention a few things. First, you are referring to *Roe* v. *Wade* in 1973, which said that even in the third trimester States could not prohibit abortions for the mother's life or health. A couple of things: No. 1, the plaintiffs in *Roe* v. *Wade*—and you'll see it on page 117 of that decision on footnote 1—specifically declined to challenge the Texas statute insofar as it forbade killing a child in the process of delivery. That is exactly the procedure that we're talking about here today.

Indeed, therefore, there is—the conclusion is easily reached that, even if *Roe* may be applied to this in the future by a court that interprets *Roe* to extend it, they would have to make a new interpretation of the Constitution to do so. *Roe,* as it stands, would not even apply to this. In fact, it left it explicitly undecided, and that law prohibiting killing in the process of delivery is still on the Texas books today.

Mr. CANADY. The gentleman's time has expired. I believe the gentleman from South Carolina, whom I'm going to recognize now, will yield to you. The gentleman from South Carolina.

Mr. CONYERS. But, Mr. Chairman, might not the witness finish her response to my question?

Mr. CANADY. Mr. Conyers——

Mr. CONYERS. Does her time get cut off because mine is expired?

Mr. CANADY. Could you——

Mr. CONYERS. Could you just answer it for the record?

Mr. CANADY. She's going to answer, if you'll bear with us, Mr. Conyers.

Mr. CONYERS. I'll be delighted——

Mr. CANADY. You've had about—you've had about 8 minutes, and we thought you were getting additional time, so she could answer. You took up most of the time. I'm going to recognize the gentleman from South Carolina.

Mr. INGLIS. And I'd be happy to yield to you to answer, continue your answer.

Ms. ALVARÉ. Thank you very much.

Mr. CONYERS. Thank you very much, sir.

Ms. ALVARÉ. I would also mention, too, Congressman Conyers, that Lawrence Tribe, who has before this body, and other committees before, supported legally abortion on the terms of *Roe* v. *Wade,* and his book also, "The Clash of Absolutes," has acknowledged that *Roe* doesn't necessarily apply here, No. 1.

No. 2, this bill does already have a life-of-the-mother exception, and the President even—I am with the National Conference of Catholic Bishops—the President acknowledged that in a response letter to Cardinal Bevilacqua, who wrote to him about the bill, that the President understands this bill clearly to have a life-of-the-mother exception.

So—and then with regard to the next question, which is, Is this an "undue burden," which is the test set up by the *Casey* Supreme Court decision on previability decisions—now, as we all know, "undue burden" is a standard that is a little like trying to nail jello to a tree; it's difficult to understand exactly what the boundaries of it are, except that one of the things that is clear from this is that it would be an undue burden to undo or to make illegal a kind of abortion under the present law, and not because I morally support it, but because that's what the law says, if it were the case that no other kind of abortion procedure, for example, would suffice in the case of saving a mother's life.

But we know from testimony or, in fact, from a public statement made by the author of the Nation's most prominently-used textbook that, not only did he say to the American Medical News he couldn't think of a health situation that would require this in response to it, but also that, in fact, it would pose additional health burdens to the mother.

Finally, with regard to the language of this void for vagueness, in fact, the language of this—and, of course, the vagueness standard is one that must be considered in connection with the criminal statute, such as this is—the language of this is so explicitly clear, about delivering some part of the child and then killing it; it doesn't get into how the child is killed once it is partially delivered; it doesn't get into how the partial delivery is done. It, in fact, is very physically precisely explicit about partial-delivery killing and then full delivery. Not only is that something that any laywoman like myself would know who has given birth, any person who hasn't given birth would also be familiar of it, from any hearing about the birthing process, let alone a doctor who has performed thousands of abortions.

Thank you very much for that opportunity.

Mr. CONYERS. Would the gentleman allow me a comment?

Mr. CANADY. I'd be happy to.

Mr. CONYERS. I thank him very much.

I appreciate it. That's the most thorough explanation of the position of those who hold your views that I have heard. Let me ask you, why you didn't mention that the Ohio Federal court has enjoined a law similar to this. Was it because you don't know it?

Ms. ALVARÉ. No, it's because the law isn't really similar to this.

Mr. CONYERS. Oh, I see. OK. All right, then let me ask you about the other law professors who may be as constitutionally intelligent as Mr. Tribe, who we've enjoyed seeing before the Judiciary Committee over the years, who have a different view from Mr. Tribe's.

Ms. ALVARÉ. It's my understanding——

Mr. CONYERS. Do their views count for anything?

Ms. ALVARÉ. The only interpretation that I have heard contrary is that, I believe, of Walter Delinger, who I believe is within—is working for White House counsel. He has testified, even before he came to the White House, for, for instance, the Freedom of Choice Act——

Mr. CONYERS. But you haven't heard of any others?

Ms. ALVARÉ. No. In fact, it is——

Mr. CONYERS. OK, well, I'll help you there. Now the President's letter, have you heard about the President writing a letter——

Ms. ALVARÉ. I'm quite familiar with it, yes; thank you.

Mr. CONYERS. Would you address the problems that he has raised with this measure, if we have time and if the gentleman from South Carolina will continue to yield?

Mr. INGLIS. I'd be happy to yield.

Ms. ALVARÉ. Thank you.

The President's primary objection is what he thinks is required by *Roe* v. *Wade* in terms of "health" of the mother. It has been explained to the White House Counsel's Office that *Roe* v. *Wade* explicitly did not consider an abortion procedure, or what is called an abortion procedure, in which the child is partially delivered before being terminated. When asked to comment on this explicitly and to counter that argument that *Roe* does not apply, we have had no response from the White House so explicit.

Mr. CONYERS. There's a lot more in that letter. Do you know——

Mr. CANADY. I'm sorry, the gentleman's time has expired. We will have a second round, and you can—I'd be happy for you to continue. I would yield time now to Ms. Alvaré, if there are any additional comments that you want to make in response to the question.

Ms. ALVARÉ. Just my understanding, which is, in part, a question to the Congressman, that the nub of the President's problem with this bill as it stands is, as I've mentioned, the absence of a "health" exception. The nub of the constitutional response to that is that there is no basis for claiming that *Roe* applies here and, thus, requires the "health" exception. And that—there are a lot of other things that were said in the letter, but none that go explicitly to your question about the constitutional rationale here. It was more about his feelings about the issue generally.

Mr. CANADY. I don't have any additional questions. Mr. Hyde. I'm sorry, Mr. Conyers and then Mr. Hyde.

Mr. CONYERS. Well, I thank you very much.

Ms. ALVARÉ. Thank you.

Mr. CONYERS. This is very helpful.

Let us turn now to the testimony of Professor Seidman from Georgetown Law School. You're familiar with his testimony, I presume?

Ms. ALVARÉ. Yes.

Mr. CONYERS. OK. He testified pretty clearly that the measure that we're discussing is unconstitutional. Do you take exception to the statements that he made?

Ms. ALVARÉ. Yes, I do, because in the end——

Mr. CONYERS. In which respects?

Ms. ALVARÉ. I'll tell you, his major contention is that *Roe* v. *Wade* requires a "health" exception and that this bill, under the *Casey* test, is an undue burden. And I can't explain myself any more clearly than I have previously, that you simply cannot make the legal case that *Roe* applies to a procedure whereby the child is partially delivered——

Mr. CONYERS. Sure.

Ms. ALVARÉ [continuing]. Before being killed.

Mr. CONYERS. You've made that very clear.

Ms. ALVARÉ. Yes.

Mr. CONYERS. Professor Seidman doesn't understand it; and the President through his counsel don't understand it.

Ms. ALVARÉ. I'm not sure it's a question of understanding or simple—there hasn't been a clear response to it. I'm not sure if they understand or not, in so much as we simply don't know what their response to that argument is.

Mr. CONYERS. Well, I thought the President raised *Roe* very explicitly in his letter.

Ms. ALVARÉ. But we, in return, spoke——

Mr. CONYERS. You need some clarification on the President's letter, is that it?

Ms. ALVARÉ. No, actually, I'm very clear on the President's letter. He raised *Roe* v. *Wade*. He said it requires——

Mr. CONYERS. But then you don't think he—you don't know if he understands it or not, but you don't need any further explanation on the letter?

Ms. ALVARÉ. What I can say is that, from all the explanation that he has given publicly, it is clear that either he disagrees with our argument regarding *Roe*—it is not that he doesn't know it, because we have communicated to the White House; he disagrees with it. All I'm saying is I don't know why he disagrees or on what basis he disagrees——

Mr. CONYERS. Well, wouldn't another letter help clear that up in your mind?

Ms. ALVARÉ. We would be happy for any communication from the White House that would go exclusively to the constitutionality being raised——

Mr. CONYERS. Well, then you do need another letter.

Ms. ALVARÉ. Well, we have asked for one, yes. I mean, we have asked——

Mr. CONYERS. Yes, OK.

Ms. ALVARÉ [continuing]. For communication, but——

Mr. CONYERS. May I join you in that request? I think the more light we shed on this, the better we will respect each other's positions. And, apparently, the President's position is not clear now.

Ms. ALVARÉ. We would be very, very pleased——

Mr. CONYERS. OK.

Ms. ALVARÉ [continuing]. To have the President's position brought to the American public and explained in as excruciating of detail as is possible.

Mr. CONYERS. Well, I don't know why we have to excruciating about it. How about just a simple explanation.

Ms. ALVARÉ. Simply by just adding vocabulary——

Mr. CONYERS. How about just a simple explanation that everybody in America, including you, can understand?

Ms. ALVARÉ. We would be delighted for that.

Mr. CONYERS. All right, count me in as one of your allies on that subject.

Now if it turns out, Attorney, that the Ohio court that enjoined a law similar to this one, that you happen to be incorrect, heaven forbid, but just in the possibility that you might be wrong, just in the possibility that Professor Sideman might be right, just in the possibility that the President of the United States with his infinite number of attorneys and advisors and counsel might happen to be correct, and might be explaining this as plainly as they can, would that have an effect upon your appreciation for what you have said here today?

Ms. ALVARÉ. Two brief points: one——

Mr. CONYERS. I said, would it, yes or no?

Ms. ALVARÉ. I cannot answer it without——

Mr. CONYERS. You can't answer yes or no?

Ms. ALVARÉ [continuing]. Saying that the Ohio law is not——

Mr. CONYERS. Oh, no, that's your opinion. I said, suppose it turned out differently. I understand what your view is. If it turned out differently, yes or no, would it affect your position?

Ms. ALVARÉ. I'm sorry, I can't agree with the premise that the President's interpretation——

Mr. CONYERS. I didn't ask you to agree with the President's premise. I asked you to answer the question.

Ms. ALVARÉ. I'm sorry, sir, I am not able to with those premises.

Mr. CONYERS. Well, thank you very much anyway.

Ms. ALVARÉ. Thank you.

Mr. CANADY. Mr. Hyde.

Mr. HYDE. Yes, thank you.

You understand, Ms. Alvaré, sometimes this has the form of a dialog but the reality of a monolog; you understand that. [Laughter.] You've kind of got to cope in these hearings.

The President has great lawyers, and because he's the President, they're always right. Lawyers never disagree, isn't that your experience, Ms. Alvaré?

Ms. ALVARÉ. Oh, absolutely. Absolutely. [Laughter.]

What I'm simply trying to communicate is that, in all honesty, with not only our belief, but also with the addition of some lawyers who do not traditionally support our position—and Lawrence Tribe is a very good example of that—there is—there is a significant body of belief among lawyers, which is almost as good as you're going to get in most cases, that one cannot see how *Roe* could directly apply here, and that even if a court were to say in the future, "We're going to extend *Roe* to apply here," that even then this would fail under the Casey "undue burden" test.

Mr. HYDE. Well, even, I understand, Justices on the Supreme Court can disagree, and that decisions occasionally come down 5-to-4; isn't that your experience?

Ms. ALVARÉ. Absolutely.

Mr. HYDE. Now we have a press release from Planned Parenthood Federation of America for immediate release March 21. It's on our table somewhere. And it says, "The truth is that the D&X"—I suppose that's their shorthand for partial-birth abortion. I don't know where "D&X" is found; it's not in the medical books; it's not in any dictionary, but partial-birth abortion is in the statute anyway, or in the bill; it's not a statute yet.

"The truth is that the D&X procedure is only used when the woman's life or health is in danger or in cases of fetal anomaly."

Now Dr. Haskell has never made any such claim. In fact, he wrote, and I quote, he "routinely performs this procedure on all patients 20 through 24 weeks." And he also said 80 percent are purely elective. And Dr. Haskell has done over a thousand of these.

Where do you think Planned Parenthood gets the idea that it's only used when the woman's life or health is in danger or in cases of extreme fetal anomaly?

Ms. ALVARÉ. My understanding from eight years of reading Planned Parenthood literature day-in and day-out is that this is a claim made to generate public sympathy for the continuation of the partial-birth abortion, because there simply isn't the evidence based on the words from the abortionists themselves, which is the best evidence we have, to justify such a statement.

Ms. COSTELLO. They might be referring third trimester.

Mr. HYDE. He might—they might be referring to third trimester?

Ms. COSTELLO. The third trimester as opposed to second trimester.

Ms. ALVARÉ. Dr. Haskell explicitly discussed the second trimester publicly and referred to them as primarily elective.

Ms. COSTELLO. Right, that's second trimester, not—but third trimester, I would imagine, is only the anomalies health of the mother or life of the mother. I think that statement——

Mr. HYDE. Well, he doesn't say that. He didn't say that.

Ms. COSTELLO. Well, 26 weeks I think is still considered second trimester.

Ms. ALVARÉ. May I also offer, with regard to the National Abortion Federation's statement in a 1993 letter that I believe has been part of the record in these hearings before, they pointed out that, with late-term abortions in general, second and third trimester, they cited many causes, including youth, psychiatric, emotional, lack of health insurance, financial problems, and so forth. So that claim is not, with regard to third-trimester abortions, is not even made by those who are the trade association themselves.

Mr. HYDE. Thank you.

Mr. CANADY. Mrs. Schroeder.

Mrs. SCHROEDER. Mr. Chairman, this has been a long day, and I must say I'm not pleased at how this has gone on. I've been here since 2 o'clock. So I respect the witnesses, and I thank the witnesses for being here.

And I would like to investigate something that I think the witnesses were trying to talk about, and that is the health of the mother and whether that should be a valid medical consideration. And I think, Ms. Costello, you were trying to address that and got cut off, if I remember.

Ms. COSTELLO. Yes, I was.

Mrs. SCHROEDER. Would you like to talk about this very difficult issue of whether do you have to have a guarantee you're going to die or can it be a serious health issue, because that's really what we're trying to deal with here?

Ms. COSTELLO. I think that's the big question and the big problem. One of the things that is a problem for me is I don't believe I fall under the life exception in this bill. My understanding is that no other procedure or no other—there can be no other way to save the mother's life. My doctors would have performed a cesarian section, even though I have a list of numerous amount of doctors who felt that was not safe for me at all. The other option might have been the dismembering of my daughter, which I would have had a very difficult time with that. I would not be pregnant again today because it would have been very difficult to diagnose her anomalies.

As far as health, yes, my health was definitely threatened. That is not a question. It is a question as to whether or not my life was threatened. There was a concern that my uterus could rupture, due to the 9¾ pounds of fluid. There was concern, if Katherine came on her own, because of her rigidity and her stiffness and her position, that my cervix could rupture, and it would cause hemorrhaging. I don't know that these can be proven in a court of law.

Mrs. SCHROEDER. So it's the issue of life, your health, and your reproductive health, being able to preserve those?

Ms. COSTELLO. And this may not mean much to any of you, but shortly after the procedure I recovered as if I had had a vaginal delivery. I went to the park with my children. My son hugged me and said, "Mommy, you're back." I had my health, and that is something that I am grateful for every day of my life. That is the gift that my daughter's life taught me, is that God gave us the gift of life and the gift of health, and we are to appreciate that every day. And I am grateful for that every day. And this procedure gave me my health and the ability to carry this baby, who may someday grow up to be President—I hope not—here, but who has health. And it gave us our health and our life.

Mrs. SCHROEDER. Do you still consider yourself pro-life?

Ms. COSTELLO. Absolutely.

Mrs. SCHROEDER. Do you find it uncomfortable sitting at the table where you are?

Ms. COSTELLO. This has been unbelievable for my family and for me. It has opened my eyes. I have met people I thought I would never meet. I have found them to be interesting and kind. I have learned that we can all have different views and different views and still be human beings, and I have gained a lot of respect for a lot of people on both sides of this issue and I have lost a lot respect for a lot of people on both sides of this issue.

Mrs. SCHROEDER. Ms. Line, would you like to add anything or—you've been very quiet.

Ms. LINE. Well, I think in my own personal case, with the hydrocephaly, I think that the very first doctor who spoke said that this procedure would definitely be necessary with hydrocephalic babies, and that had nothing to do with a life exception. My life was not in danger, no, it wasn't, but my baby could not survive. And this was the best procedure for me to make it so I could have babies in the future.

Mrs. SCHROEDER. And is that because they knew of no other procedure in which your organs would remain intact or were apt to main intact? Is that——

Ms. LINE. Yes, it's my understanding the only other way that this could have been done would have been with a cesarian section, and, as you all know, it's major surgery and recovery time, and all of that stuff; mortality rate.

Mrs. SCHROEDER. And so you would be very similar to Ms. Costello in that you're talking about health——

Ms. LINE. Yes.

Mrs. SCHROEDER [continuing]. And reproductive health?

Ms. LINE. Yes.

Mrs. SCHROEDER. And you feel, even as a conservative, that that is your right as an American, to be able to have that discussion with your doctor?

Ms. LINE. Yes, exactly.

Mr. CANADY. Without objection, the gentlelady will have three additional minutes.

Mrs. SCHROEDER. Thank you.

Has this been a difficult afternoon for you?

Ms. LINE. As I mentioned before, my husband and I are very private people. I mean, this was the worst nightmare of our lives. Some of my best friends don't even know all the gory details, and here I am telling the world. So, yes, it was very difficult.

Mrs. SCHROEDER. Well, I—I relate so much to what you're saying, and I—maybe I internalize all of this too much. I am very envious of any colleague from Michigan—I'm sorry.

Mr. Chairman, I must say that this has been the most difficult thing, and I do feel we're being tried as witches, and I can't wait to get out of this bloody place. This is not the America I know.

Mr. CANADY. Mr. Inglis.

Mr. INGLIS. I am sorry the gentlelady left because I was very interested in asking her to defend the Planned Parenthood statement here. I wish we had somebody from that organization present. It's a most amazing statement in this press release. It's terribly misleading.

This is the statement. It says, "The truth is that the D&X procedure is only used when the woman's life or health is in danger or in cases of extreme fetal abnormality." That is the statement of Planned Parenthood Federation of America, the largest abortion provider in the United States of America.

Ms. Alvaré, would you like to respond to that sentence in this press release? And if there are any media folks left, I surely hope that they dissect and listen carefully to the dissection of the absolute inaccuracy of that statement in this very irresponsible press release.

Ms. ALVARÉ. Planned Parenthood makes that statement without reference to being either second- or third-trimester partial-birth abortions. They're saying it across the board. At the time that statement's being made, there is not only in the record of prior congressional hearings, but also in public statements that have been printed in everything from the New York Times to the American Medical News, and in statements made in trial transcripts in Ohio from both Dr. McMahon and Dr. Haskell, to the effect that they, Dr. McMahon doesn't really make distinctions between when—or Dr. Haskell, especially in 20 to 24 weeks, he says that 80 percent are elective.

He, himself, in fact, as someone who is not board-certified and has no admitting privileges at a local hospital for difficult situations, avoids difficult situations where, say, the mother's health is seriously compromised, let alone where the mother's life is at stake, especially given that it's a 2- to 3-day procedure.

There are also statements on the record from Dr. McMahon as to the percentage of abortions he does that are elective. There is also the letter that he submitted to the subcommittee previously that lays out the reasons why he does these abortions. And, as has been summarized before, large percentages of them are for things like what he calls depression. Some he calls nonelective—in other words, the common understanding of that is mandatory, must have from a medical point of view—are for reasons like youth. And so we have in the public record clear evidence explicitly to the contrary of the Planned Parenthood statement for all to see.

Mr. INGLIS. Do you have any idea why they persist in making that statement? This is a common pattern. These folks, these purveyors of abortion, have made this statement repeatedly. Do you have any explanation as to why they would have continued to repeat that line of disinformation?

Ms. ALVARÉ. Part of my expertise with the last five years has been as full-time media and communications director on this issue, and my not only anecdotal experience, but also what has emerged from studies of coverage of abortion, shows that—claims that abortion advocates receive more favorable coverage, including when their claims are erroneous or, in fact, the opposite of the truth. And so I think Planned Parenthood is probably aware that that statement will get printed and will affect people's opinion on this bill, even though they are aware it is not true.

Mr. INGLIS. All the more reason, Mr. Chairman, to congratulate you on the holding of this hearing. I think this has been a wonderful day because this really does show the truth of this situation. And as unseemly as it is and as unpleasant as it is for people like Mrs. Schroeder to face that truth, it's the truth. This is a terribly awful procedure that we've already heard is performed not for reasons of health exclusively, as Planned Parenthood wishes us all to believe, as though they can continue that line of deception. Thankfully, here we've gotten to the truth; that is not the case. And I appreciate you holding the hearings.

Mr. CANADY. The gentleman's time has expired.

Again, I want to thank each of the witnesses on this panel. We appreciate your taking the time to be with us.

The subcommittee is adjourned.

[Whereupon, at 3:47 p.m., the subcommittee adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING

Fact Sheet by Rep. Charles T. Canady

"Fetal Death" or Dangerous Deception? The Effects of Anesthesia During a Partial-Birth Abortion

The claim that anesthesia given to a pregnant woman kills her fetus/baby before a partial-birth abortion is performed has ***"absolutely no basis in scientific fact,"*** according to Dr. Norig Ellison, the president of the American Society of Anesthesiologists. It is ***"crazy,"*** says Dr. David Birnbach, the president-elect of the Society for Obstetric Anesthesia and Perinatology.

Despite such authoritative statements, this medical misinformation is still being disseminated. Here are a few examples:

ABORTION ADVOCATES

Kate Michelman of the National Abortion Rights Action League (NARAL)

One of the leading proponents of the "anesthesia myth" is Kate Michelman, president of the National Abortion Rights Action League (NARAL). For example, in an interview on "Newsmakers," KMOX-AM in St. Louis on Nov. 2, 1995, Ms. Michelman said:

> *The other side grossly distorted the procedure. There is no such thing as a 'partial-birth'. That's, that's a term made up by people like these anti-choice folks that you had on the radio. The fetus-- I mean, it is a termination of the fetal life, there's no question about that. And the fetus, is, before the procedure begins, the anesthesia that they give the woman already causes the demise of the fetus. That is, it is not true that they're born partially. That is a gross distortion, and it's really a disservice to the public to say this.*

Dr. Mary Campbell of Planned Parenthood

Prior to the November 1, 1995, House vote on the bill, Planned Parenthood circulated to lawmakers a "fact sheet" titled, "H.R. 1833, Medical Questions and Answers," which includes this statement:

> "Q: *When does the fetus die?*
>
> "A: *The fetus dies of an overdose of anesthesia given to the mother intravenously. A dose is calculated for the mother's weight which is 50 to 100 times the weight of the fetus. The mother gets the anesthesia for each insertion of the dilators, twice a day. This induces brain death in a fetus in a matter of minutes. Fetal demise therefore occurs at the beginning of the procedure while the fetus is still in the womb."*

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THE PRESS

The New York Daily News

> *The fetus is partially removed from the womb, its head collapsed and brain suctioned out so it will fit through the birth canal. The anesthesia given to the woman kills the fetus before the full procedure takes place. But you won't hear that from the anti-abortion extreme. It would have everybody believe the fetus is dragged alive from the womb of a woman just weeks away from birth. Not true.* (Editorial, Dec. 15, 1995)

USA Today

"*The fetus dies from an overdose of anesthesia given to its mother.*"
(Editorial, Nov. 3, 1995)

The St. Louis Post-Dispatch

"*The fetus usually dies from the anesthesia administered to the mother before the procedure begins.*" (News story, Nov. 3, 1995)

Syndicated Columnist Ellen Goodman

Syndicated columnist Ellen Goodman wrote in mid-November that, if one relied on statements by supporters of the bill, "*You wouldn't even know that anesthesia ends the life of such a fetus before it comes down the birth canal.*"

The Truth

"Medical experts contend the claim is scientifically unsound and irresponsible, unnecessarily worrying pregnant women who need anesthesia."
(*American Medical News*, January 1, 1996)

"[A]nesthesia does not kill an infant if you don't kill the mother."
(Dr. David Birnbach quoted in *American Medical News*, January 1, 1996)

"I am deeply concerned, moreover, that widespread publicity... may cause pregnant women to delay necessary and perhaps life-saving medical procedures, totally unrelated to the birthing process, due to misinformation regarding the effect of anesthetics on the fetus." (Dr. Norig Ellison, Nov. 17, 1995, testimony before Senate Judiciary Committee)

"Drugs administered to the mother, either local anesthesia administered in the paracervical area or sedatives/analgesics administered intramuscularly or intravenously, will provide no-to-little analgesia [relief from pain] to the fetus." (Dr. Norig Ellison, November 22, 1995, letter to Senate Judiciary Committee)

Chicago Sun-Times, Thursday, January 4, 1996, p. 23

Never Let Facts Impede Ideology

Somehow the wacky idea has gotten out that giving pregnant women anesthesia is bad.

The American Society of Anesthesiologists worries that women will delay necessary or even life-saving medical procedures because they fear anesthesia will harm their fetuses. Dr. David Birnbach, of the Society for Obstetric Anesthesia and Perinatology, says cases of maternal concerns about dangers to the fetus have recently surfaced, the American Medical Association's American Medical News reported. Rep. Tom Coburn (R-Okla.), who still delivers babies, said a patient even refused epidural anesthesia during childbirth.

Birnbach and other experts uniformly insist that the fear is unfounded. Dr. Norig Ellison, president of the American Society of Anesthesiologists, told Congress that more than 50,000 pregnant women are safely anesthetized annually without ill effects to mother or fetus.

Yet some folks are saying otherwise, including Kate Michelman, president of the National Abortion and Reproductive Rights Action League. Their insistence that anesthesia administered during partial-birth abortions prevents fetal pain and causes fetal death is having an unfortunate consequence: Some women are becoming afraid that anesthesia will harm babies they're planning to have.

Ellison's group has no position on the controversial ban on partial-birth abortions, in which a live, late-term fetus is partially pulled, feet first, from the womb, stabbed in the back of the neck and its brains sucked out. But they do feel strongly about Michelman's misinformation. Birnbach said assertions that anesthesia causes fetal death in such abortions are shocking and crazy.

Ellison branded as "entirely inaccurate" a claim by an abortionist that the anesthesia eliminates fetal pain and causes brain death before the abortion. The fact is, he said, only a small portion of general anesthesia crosses the placenta to reach the fetus, depending on the amount, and none administered regionally does. It is not "absolutely known," he added, that the anesthesia even reduces the fetus' pain. "I have not spoken with one anesthesiologist who agrees with [the abortionist's] conclusion, and in my judgment, it is contrary to scientific fact. It simply must not be allowed to stand," he said.

As their evidence, pro-choicers cite a letter from an Albuquerque physician (not an anesthesiologist), Lewis Koplik, who opposes the ban. I read the letter to Ellison, who branded its conclusions "wrong" and "untrue." A dose of anesthesia massive enough to kill the fetus, as cited in the letter, places the mother's own health "in serious jeopardy," Ellison said, and should require the presence of an anesthesiologist (which is not standard practice).

Despite all this, Michelman's misinformation continues to be repeated as the unqualified truth by, for example, Sen. Carol Moseley-Braun (D-Chicago), syndicated columnist Ellen Goodman, a USA Today editorial, KMOX-AM in St. Louis and Planned Parenthood, said the National Right to Life Committee. Michelman repeated the assertion in a letter to the editor here on Sunday, attacking my support of the ban. (She also claimed I said that the anesthesia "does not affect the fetus"—which I didn't. But accuracy apparently isn't Michelman's strong suit.)

Ellison confesses to frustration that Michelman's misinformation gets circulated without challenge, while his scientific evidence is barely mentioned. Welcome, Doc, to the abortion wars, as refereed by the ever-objective media. Never let facts stand in the way of a favored ideological agenda. Not even at the expense of women's health.

Dennis Byrne is a member of the Sun-Times editorial board. E-mail: dbyrne@suntimes.com

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LEWIS H. KOPLIK, M.D., F.A.C.O.G.
[illegible]

December 5, 1995

Senator Barbara Boxer
United States Senate
Capitol Building
Washington, D.C.

Dear Senator Boxer:

I was contacted by the National Abortion Federation to see if I could support the statements made by Dr. James McMahon that the fetus, during an intact dilation and extraction abortion, was either comatose, severely depressed, or dead, as a result of the drugs administered. My initial response was I could not support that statement but that was before I had received the details of what medication Dr. McMahon used and how much he used. Having received more specific information about his technique, I have no problem supporting the statements he made in Washington, D.C., before his death. To put it in some relative perspective, I use a dose of 2 milligrams of Versed® and 25 micrograms of Fentanyl® when performing either suction curettage abortions or early second trimester dilation and evacuation (D&E) procedures. Dr. McMahon's protocol calls for 5 to 20 times more Versed® and 36 to 100 times more Fentanyl®. While I realize that these drugs' half life activity is short, these are massive doses which, I am sure, would produce the results claimed by Dr. McMahon. I am also certain anyone who would call Dr. McMahon a liar is speaking from ignorance of abortions in late pregnancy and of Dr. McMahon's technique and integrity.

I am also including a letter I FAXed your office last month which will be of value.

I shall be in El Paso for the rest of this week but could be reached by you or your staff at Reproductive Services at (915) 544-2861.

Thank you for all the work you have done combatting this terrible and dangerous piece of legislation.

Sincerely,

Lewis H. Koplik, M.D.

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